

Quality Review Board – Base/Core I&A

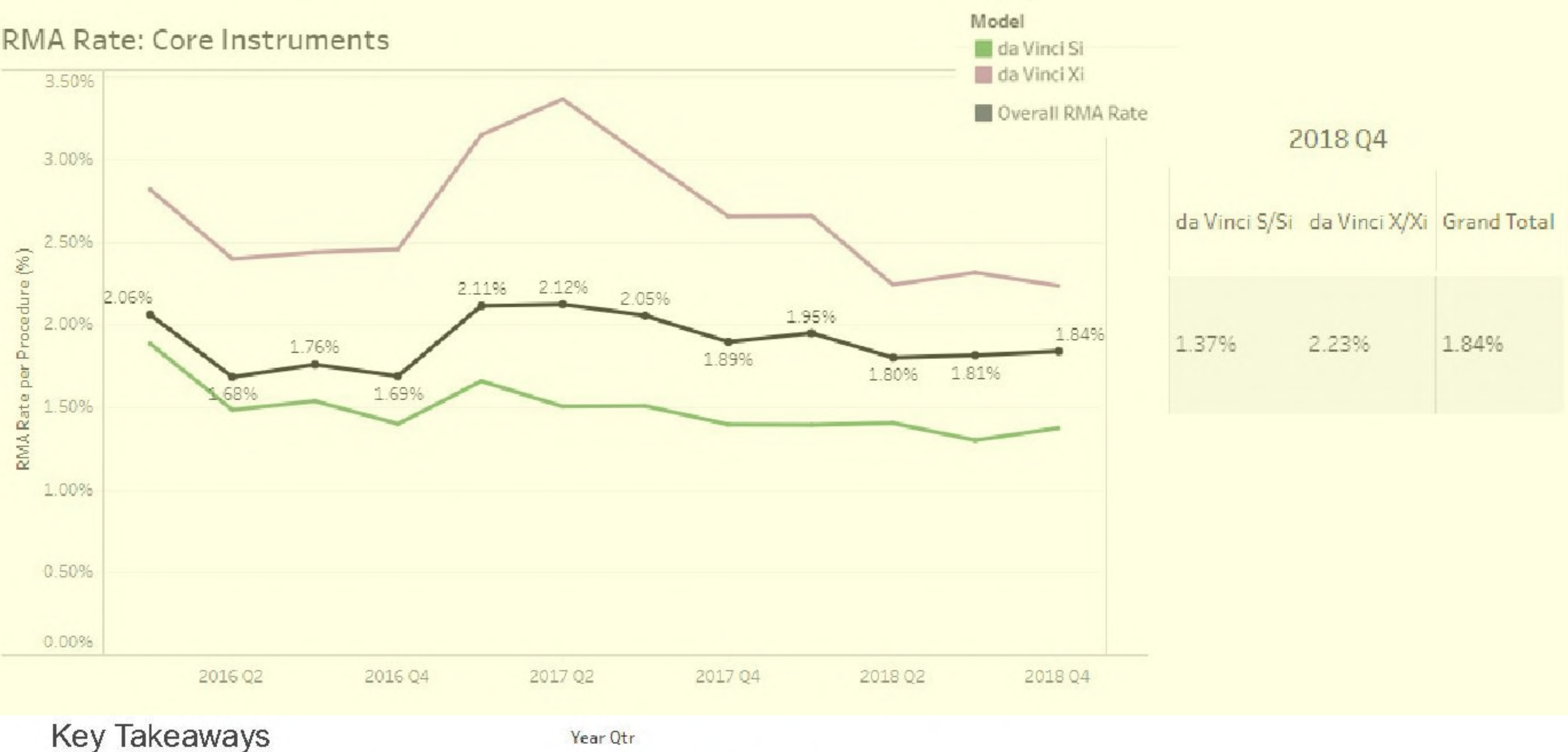
Part 2 – Product Health, Base/Core I&A

Base Instruments and Accessories through Q4 2018

Agile Item QRB-2018-Q4-DATA, Archived by ECO # C225481

Danny Brock, Mehdi Ebrahimiian, Mike Stjern, Ralph Wadensweiler, Aurorae Tran
February 8, 2019

RMA Rate - Instruments



- Key Takeaways
- Quarterly **decrease** in RMA rate for Xi, **increase** for Si
 - Q4 WIN Goal for Xi/X = **2.00%**; Actual = **2.23%** (including cancellations)
 - 2018 CIP Goal = 2.40%**

Symbol Definitions



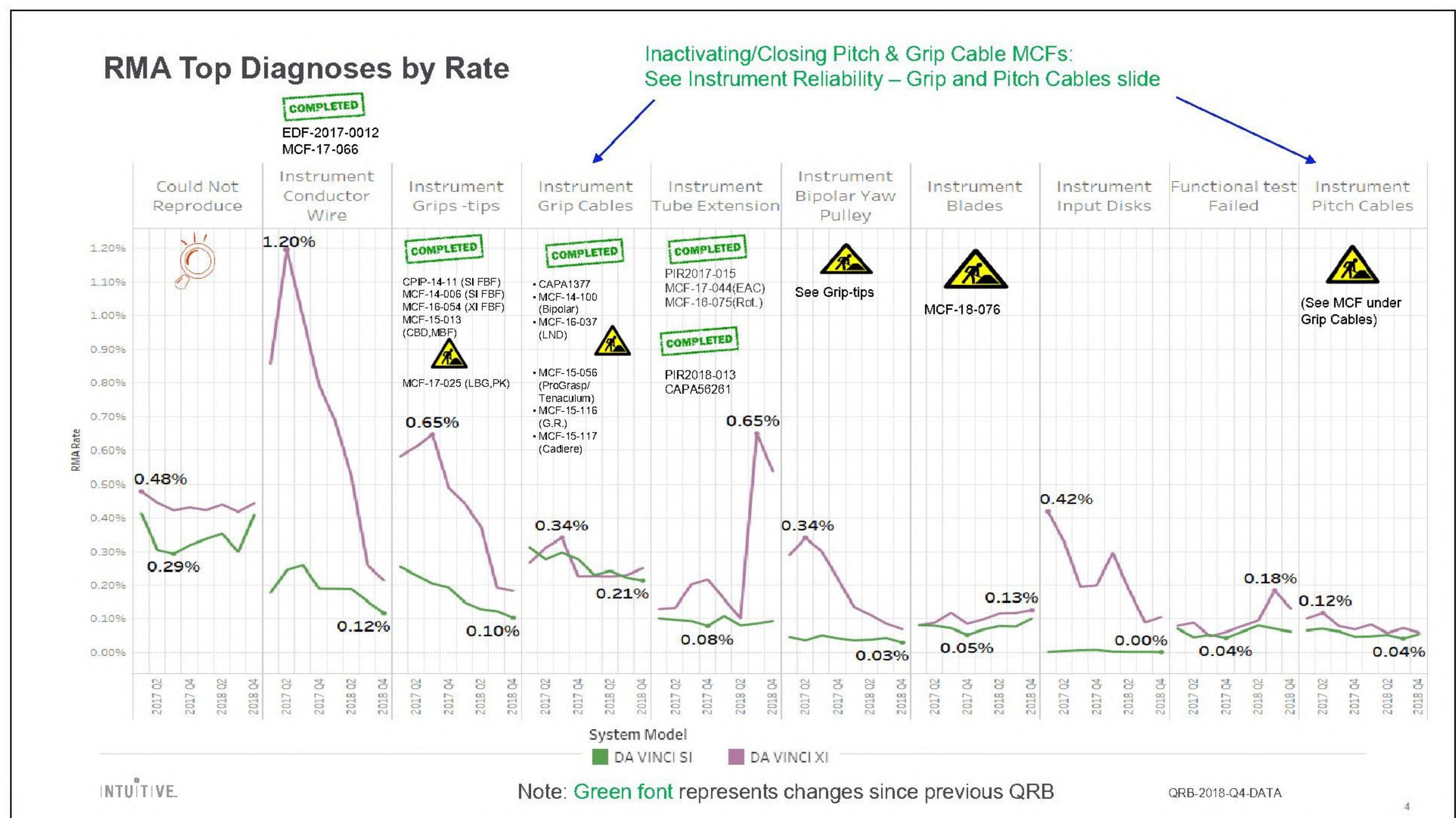
Work in progress



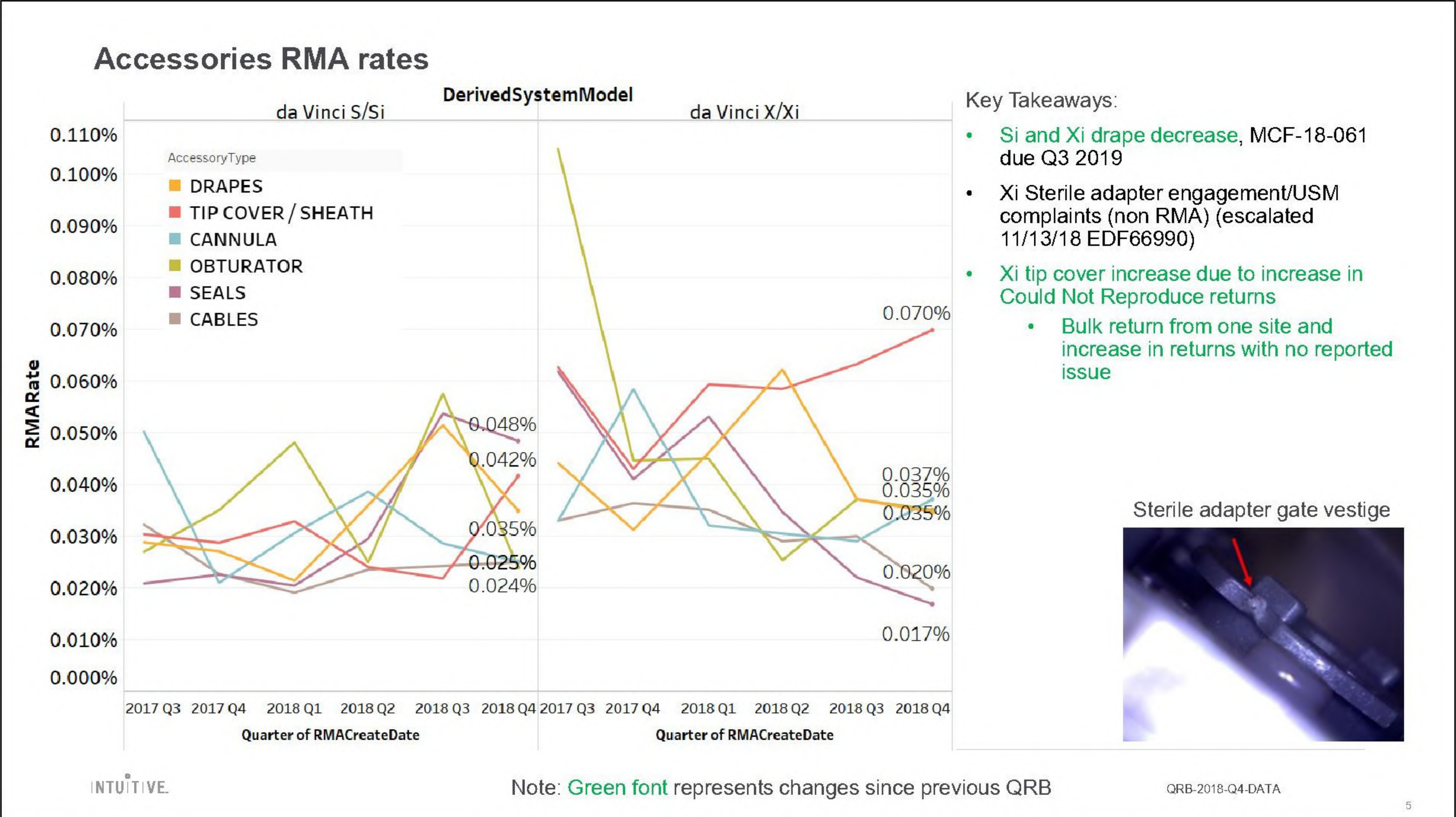
Project Completed



Monitoring

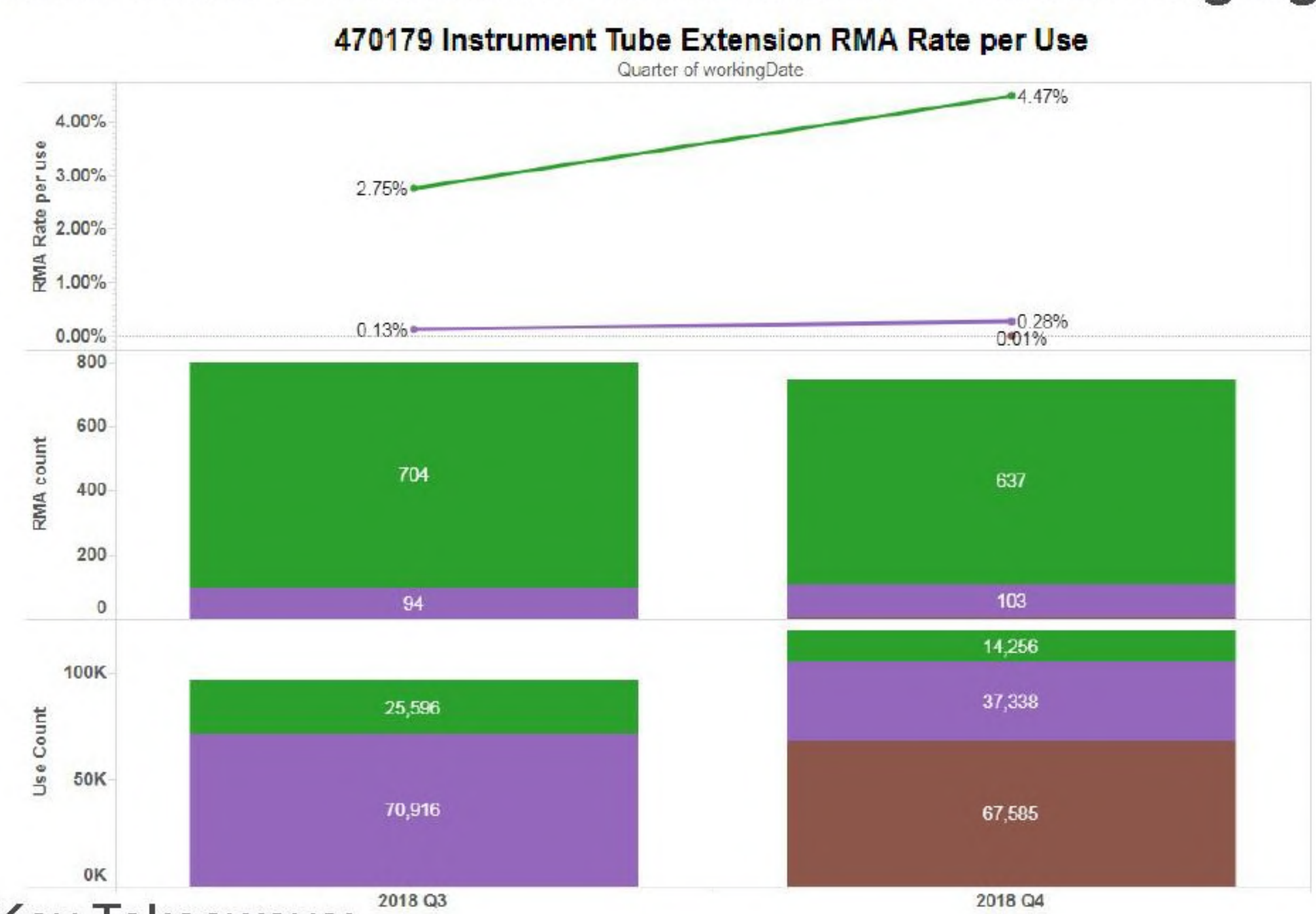


CNR – Si – increase due to cannot verify external event 404 total (+150 from last quarter)(27 more cutting, 32 more grip failure, 15 more non-intuitive, 31 more recognition, 16 more cable damage, 10 more physical damage) and expected condition 84 total (+50 from last quarter)(41 new input discs from 26 sites)(28 condensation on suction/irrigators from 4 sites)



Increase in Xi tip cover due to bulk return (24) from Sahlgrenska Universityhospital; 72 of the 96 total were CNR
For Si Seals, two sites had 6 returns each. One was mostly physical damage, the other was due to a white substance on the duckbill. FTIR results were not conclusive but pointed to it being talc or polyimide resin

MCS Tube Extension Performance – Bent/Bulging



470179 (ver 15-16) Peek 450G;
470179 (ver 17,18) Peek 90G;
470179-19 (Peek New 450G)

Bent Tube Extension



Bulging Tube Extension



Key Takeaways:

- PIR2018-013 / CAPA 56261
- PEEK 90G (green) performs worse than PEEK 450G (purple/brown)
- Production switched back to PEEK 450G in September 2018
- 450G is effective in addressing RMAs

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Note: Green font represents changes since previous QRB

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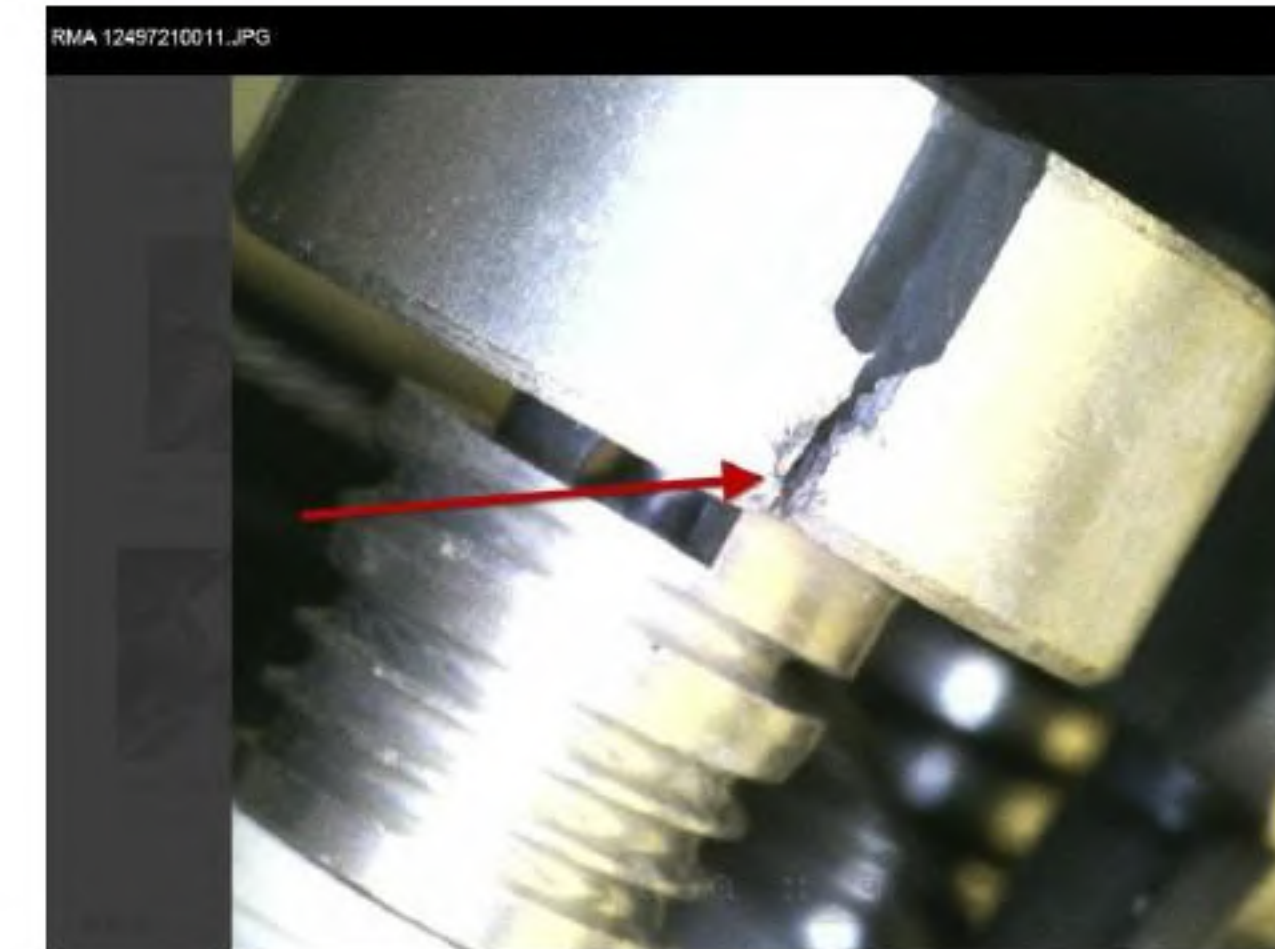
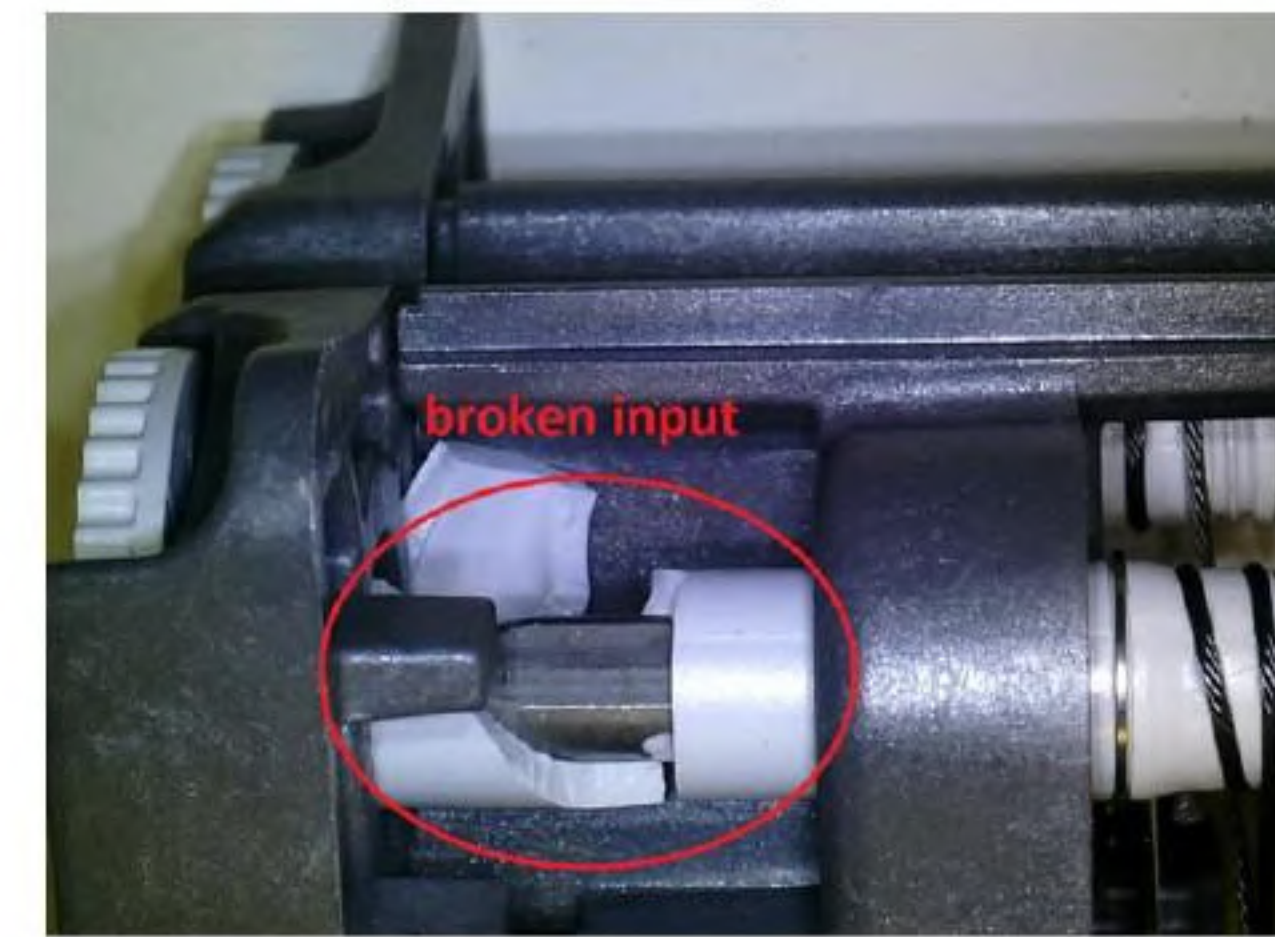
Diagnosis: Instrument Input Disks – Broken (IS4000)

Key Takeaways:

- New material for Xi Input Disks: PEEK (MCF-16-045/ EDF-2017-0015):
 - Passed Chem. Test
 - No failure when exposed to Prolystica, Mediclean Forte, and MediKlar rinse aid (25 cycles)

Status:

- Expanded project scope to include the following (MCF-18-076, due Q3 2019)
 - Comprehensive over-molded PEEK 450G qualification (PPQP testing)
 - Add clamping pulley changes to scope to address cracking observed in the field
 - Tooling complete at ChemTech



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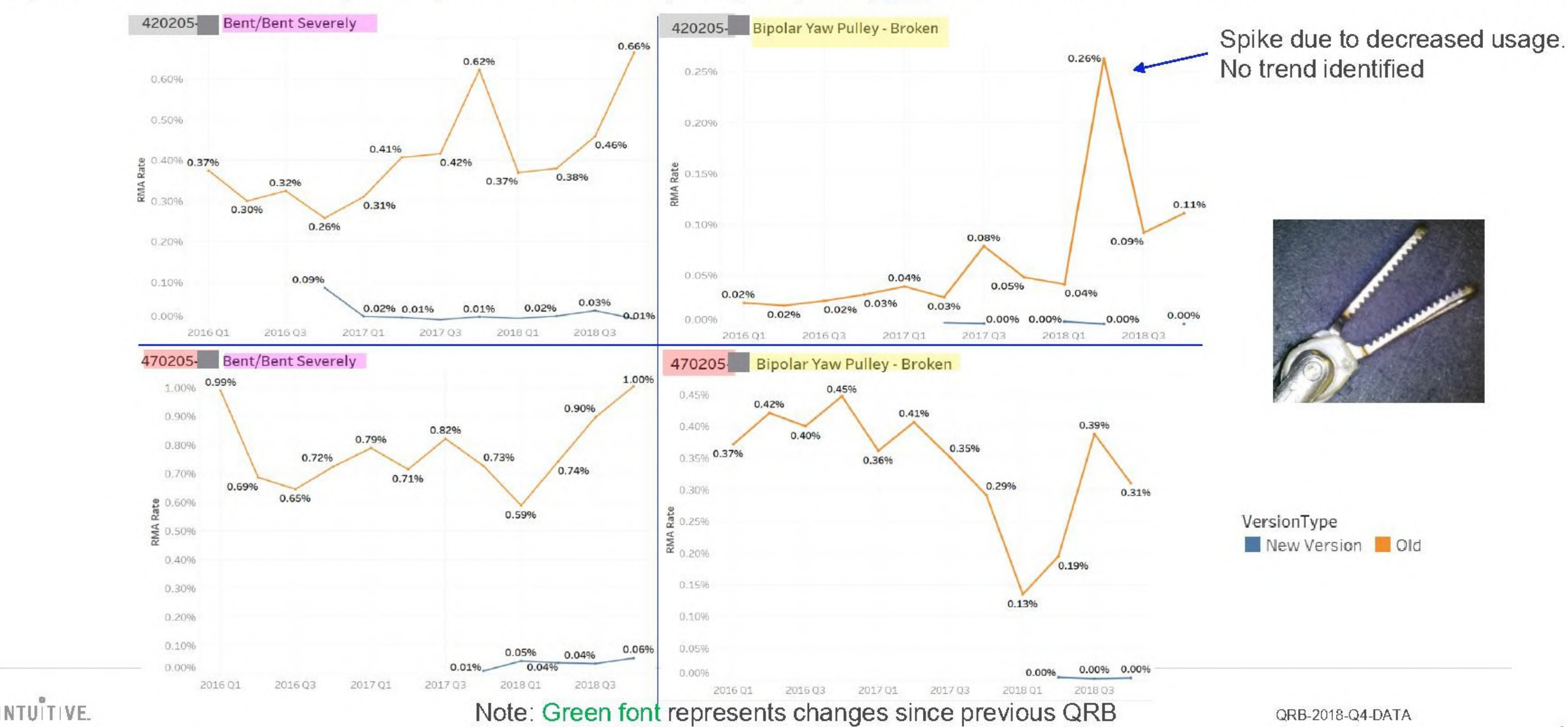
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CPIP-14-11: Bipolar Grip Improvements

Key Takeaways :

Continued improvement in bent grip and yaw pulley RMAs (EDF-2017-0020 / EDF 1035)

Bipolar instrument APL status (All except Precise and Micro): FBF, MBF, CBD, **LBG**: on APL / PK: APL Q1 2019

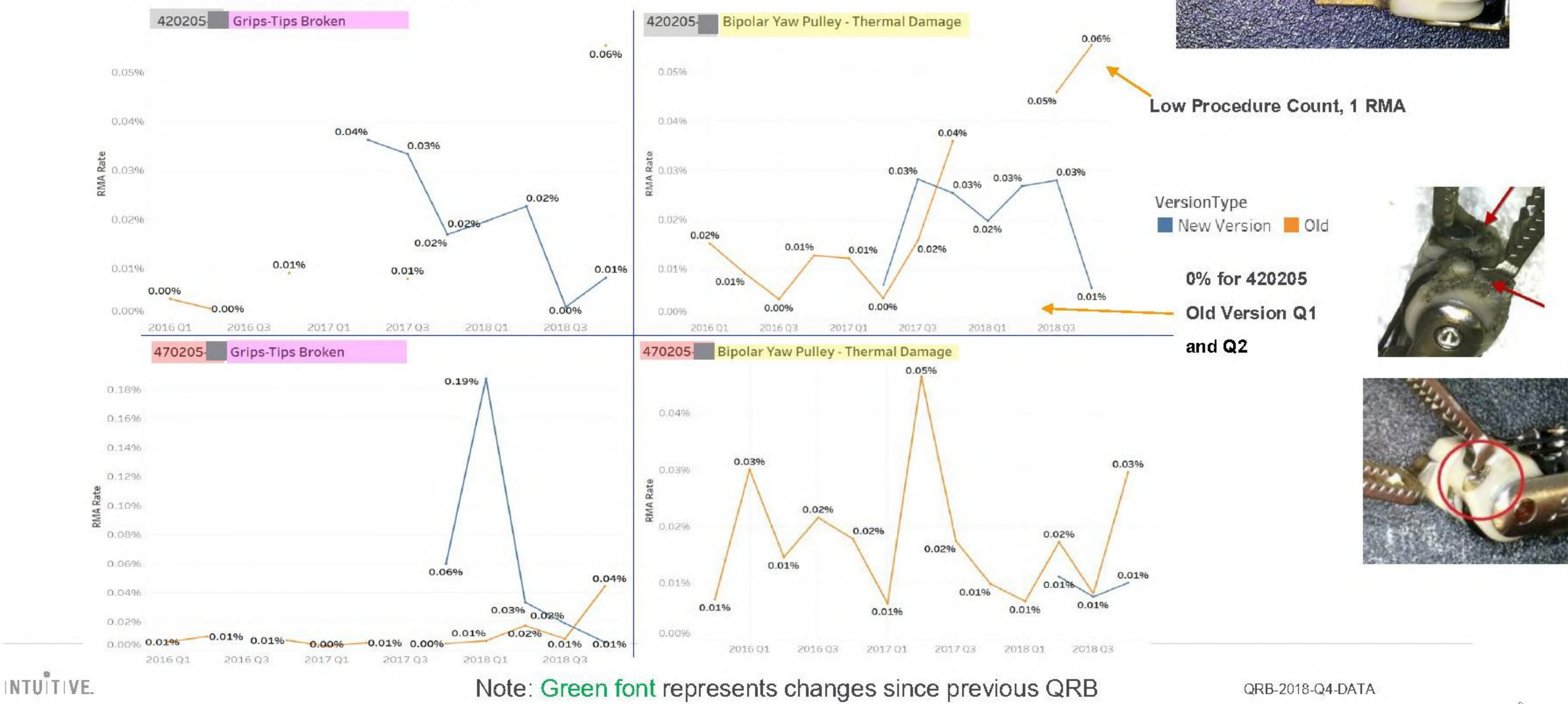


CPIP-14-11: Bipolar Grip Improvements

Key Takeaways :

Grips susceptible to breakage – 57 for Si FBF, 44 for Xi FBF (EDF-2017-0020 / EDF 1035)

- 3 breaks after hardness spec change
- Thermal damage in yaw pulleys - continuing to monitor but similar RMA rate to previous design



Instrument Reliability – Grip and Pitch Cables

ERB Decision:

Close or Inactivate Pitch and Grip Cable MCFs Due to Low RMA Rate on Remaining Instruments

MCF-15-056 / EDF-2015-0089) - Large Distal Clevis

- Completed: ProGrasp, Tip Up Fenestrated, Double Fenestrated Grasper + Med Lrg & Lrg Clip Appliers under MCF-16-060
- Remaining: Xi Tenaculum, Dual Blade Retractor, Atrial Retractor had minimal cable RMAs in 2018
- Plan to close MCF with completed instruments, Q1 2019

MCF-16-037 / EDF-2016-0043 - Small Distal Clevis

- Completed LND
- Remaining 23 small distal clevis instruments had minimal or zero RMAs in 2018
- Plan to close MCF with completed instrument (LND), Q1 2019

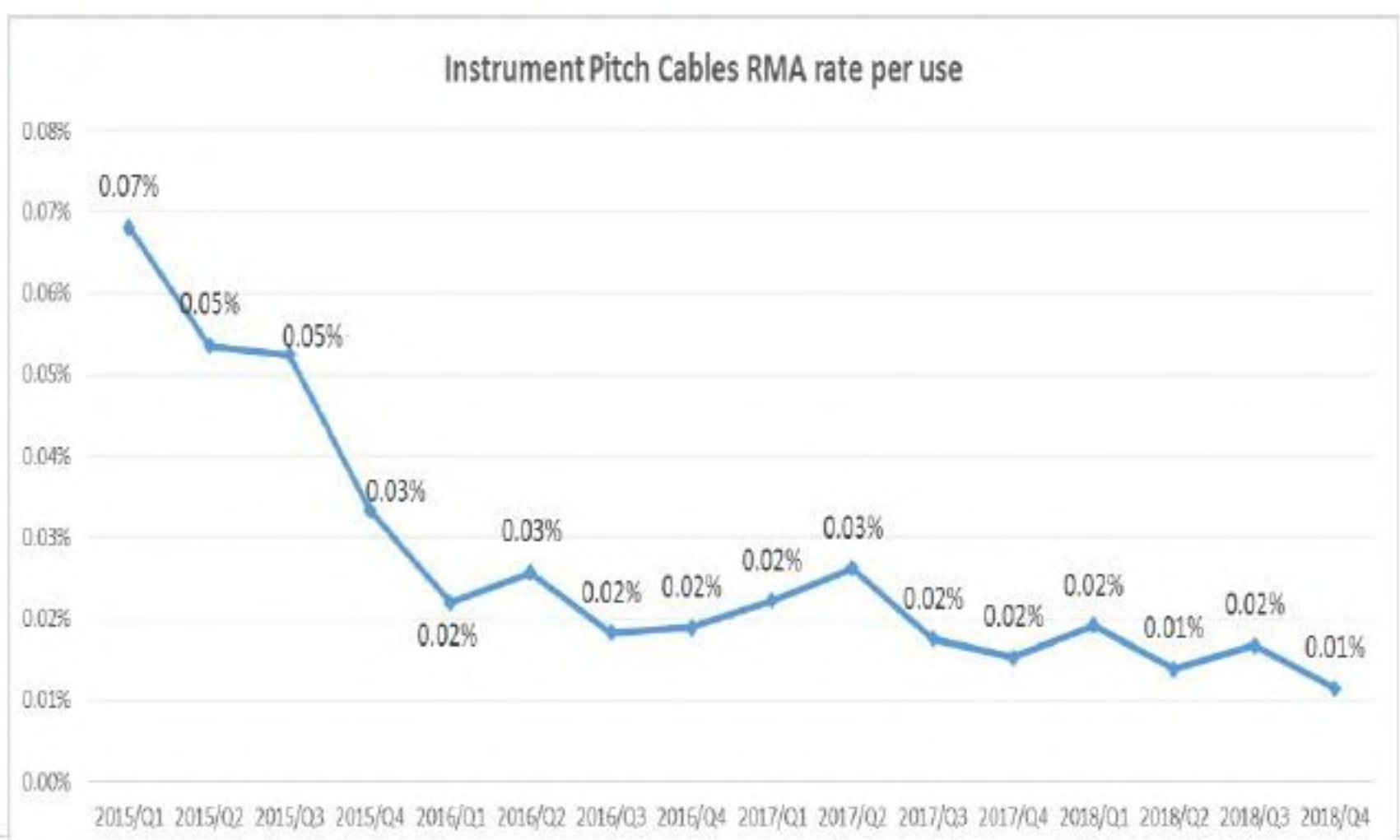
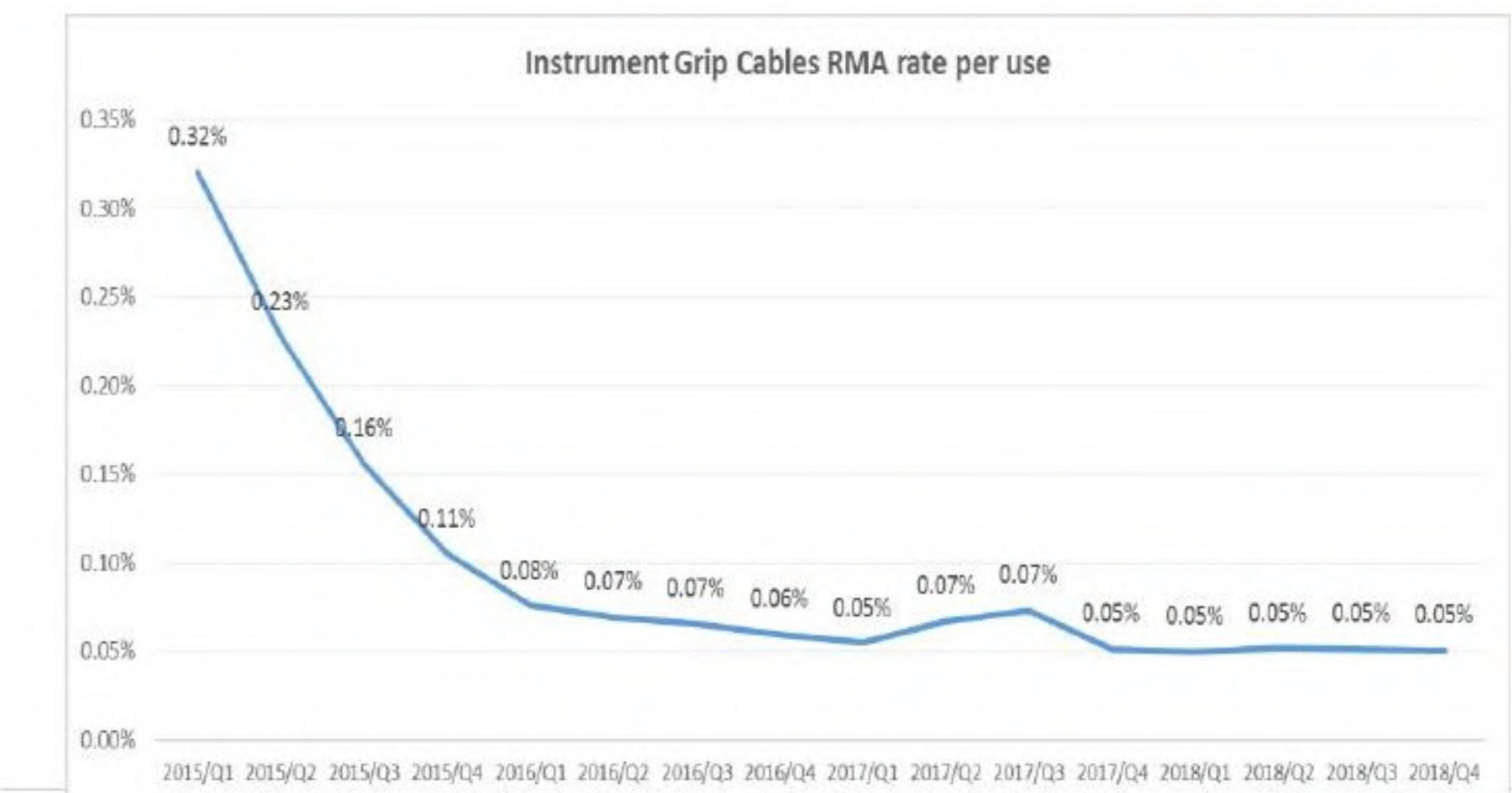
MCF-15-116 / EDF-2016-0022 - Grasping Retractors

- Xi Small Graptor had minimal pitch and grip RMAs in 2018
- Plan to inactivate MCF, Q1 2019

RMA Failure Mode:



XI Grip and Pitch Cable RMA Rates (Core Instruments)



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Xi Characteristics Contributing to Performance Gap vs. Si

Architectural / Technological Contributors:

- Higher tension
- Lower compliance, i.e., direct vs. cable drive
- Higher ROM limit on roll
- Unique input disk design vs. Si

Other contributors:

- Xi changes typically implemented prior to Si, due to project phase-in timelines and priorities

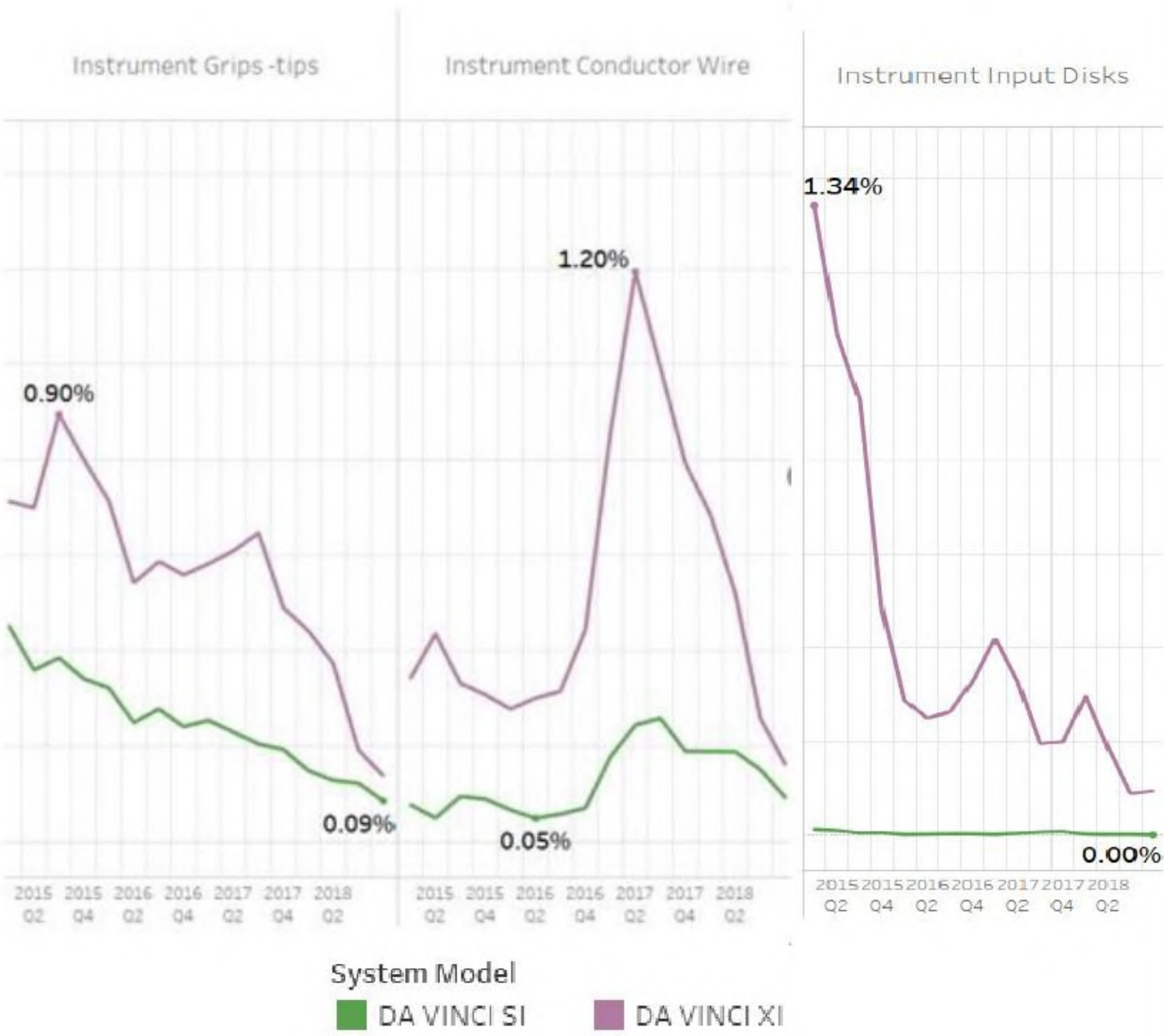
Gap Closure

Short term

- MCFs in place to address key RMAs

Long Term

- Evaluate long term changes quarterly: e.g. major design changes



Xi Characteristics Contributing to Performance Gap vs. Si - Further Explanation

Architectural / Technological Contributors:

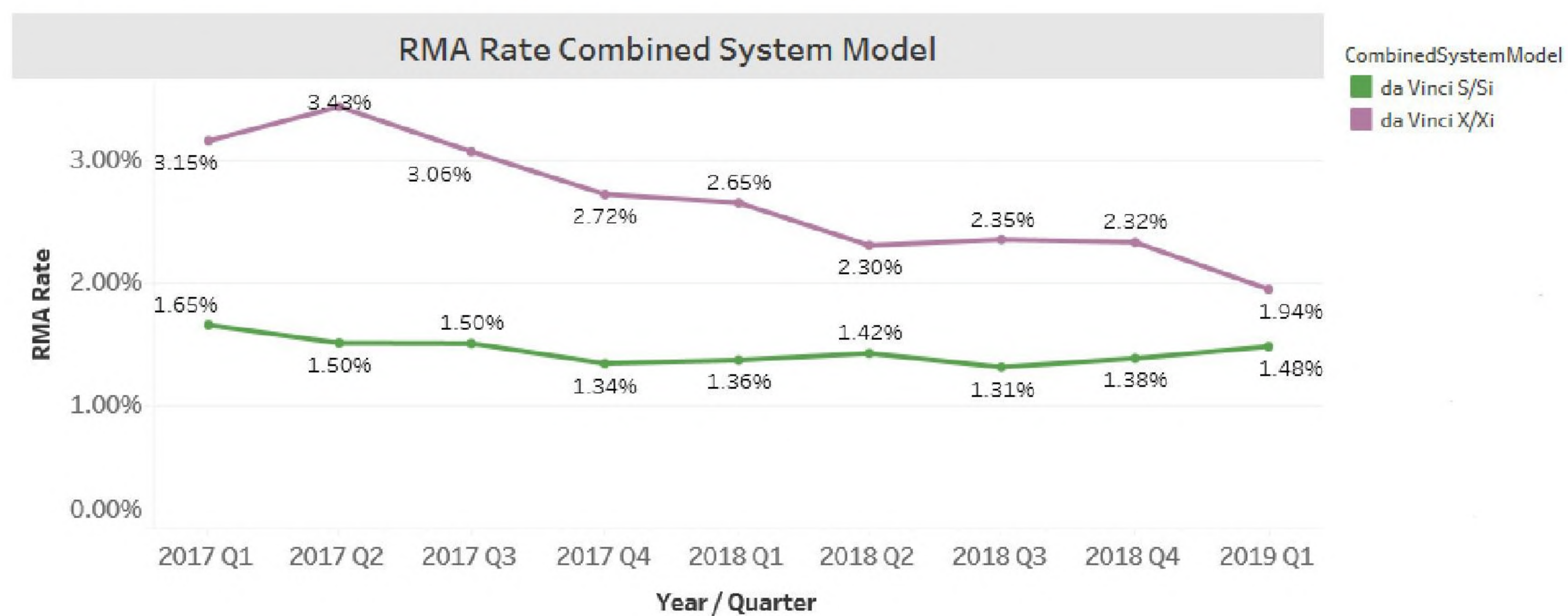
- Higher tension
 - Varies per instrument, but the cable pre-tensions (applied at manufacturing) are typically higher on Xi to compensate for the additional cable stretch due to longer cables; and in some cases Xi torque limits are set higher to compensate for additional friction losses (from waterfall bend in backend)
- Lower compliance, i.e., direct vs. cable drive
 - The input disks on the Si arm are driven via cables, which add some compliance when backdriving; on Xi the input disks are driven by "direct" coupling to motors. We believe this results in higher likelihood of instruments absorbing impact loads.
- Higher ROM limit on roll
 - Varies per instrument, but typical Si roll ROM +/-255 vs Xi roll ROM +/- 270 or +/- 310
 - Increased roll → increased hypotube wind-up → increased cable stretch & friction
- Unique input disk design vs. Si
 - Si inputs supported by bearings at top & bottom; Xi inputs are somewhat cantilevered on top; Xi input design has more plastic-insert interface.

Other contributors:

- Xi changes typically implemented prior to Si, due to project phase-in timelines and priorities
 - Examples: Bipolar conductor wire melt seal redesign & MCS PEEK 90G extension tube deployment

Xi & Si Core Instrument RMA Rates over 2 year period

Xi Core Instrument RMA rate is trending downward; while Si RMA rate remains flat



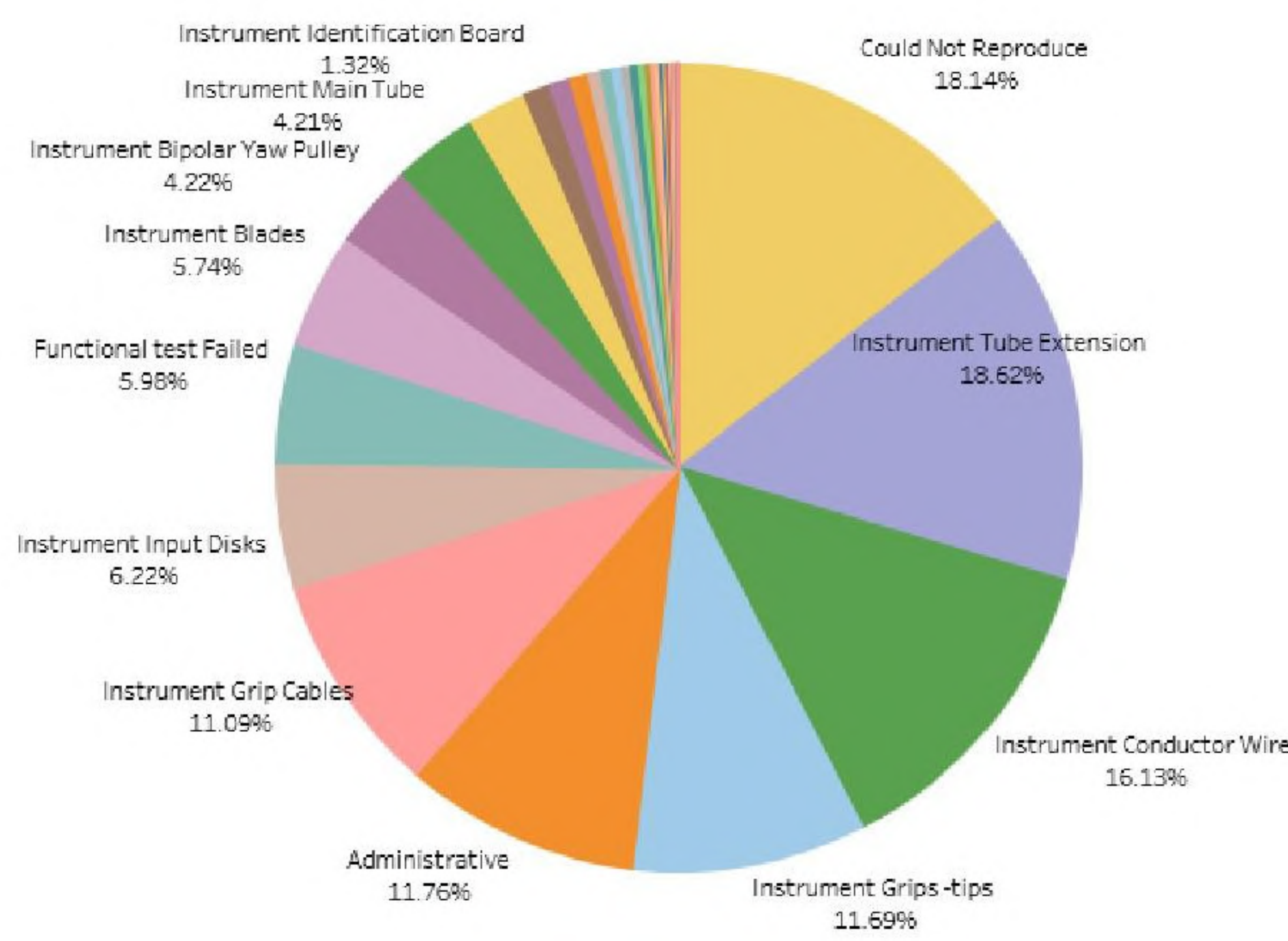
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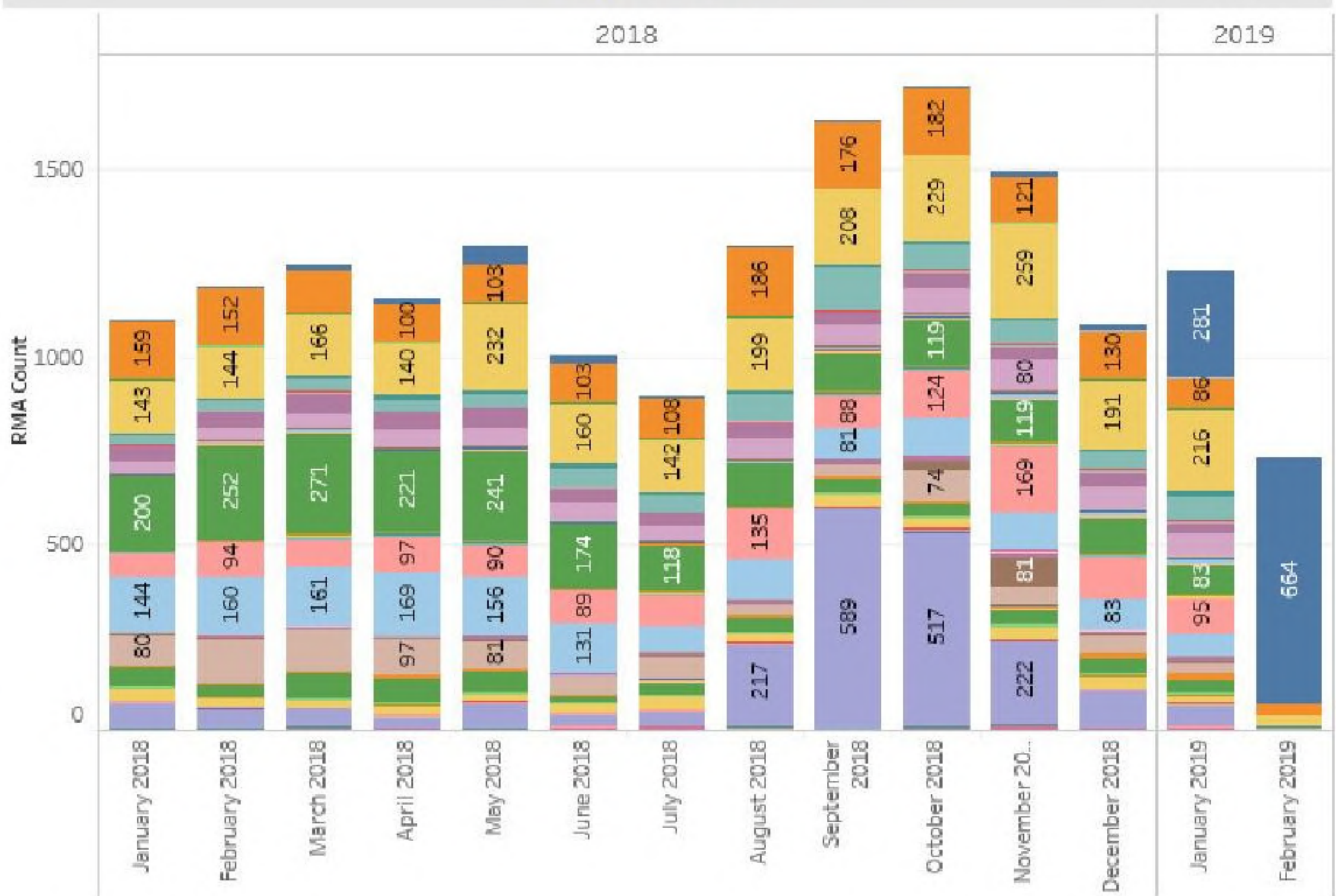
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Xi Core Instruments RMA breakdown for last 12 months

Recent Xi Instrument RMA breakdown:



RMA Pareto



Ongoing Xi Core Instrument Reliability Improvement projects

Active MCF Projects:

- MCF-16-035 – MND Grip Cables
 - Incorporating the proven MSCND wrist/grip design
- MCF-18-076 – Input Disks
 - Material change from Ultem to PEEK
- MCF-15-117 – MIM Cadiere Grips
 - (Cost project, but also includes cable improvements)
- MCF-17-055 – MIM Tip Up Fenestrated Grasper
 - (Cost project, but also includes cable improvements)

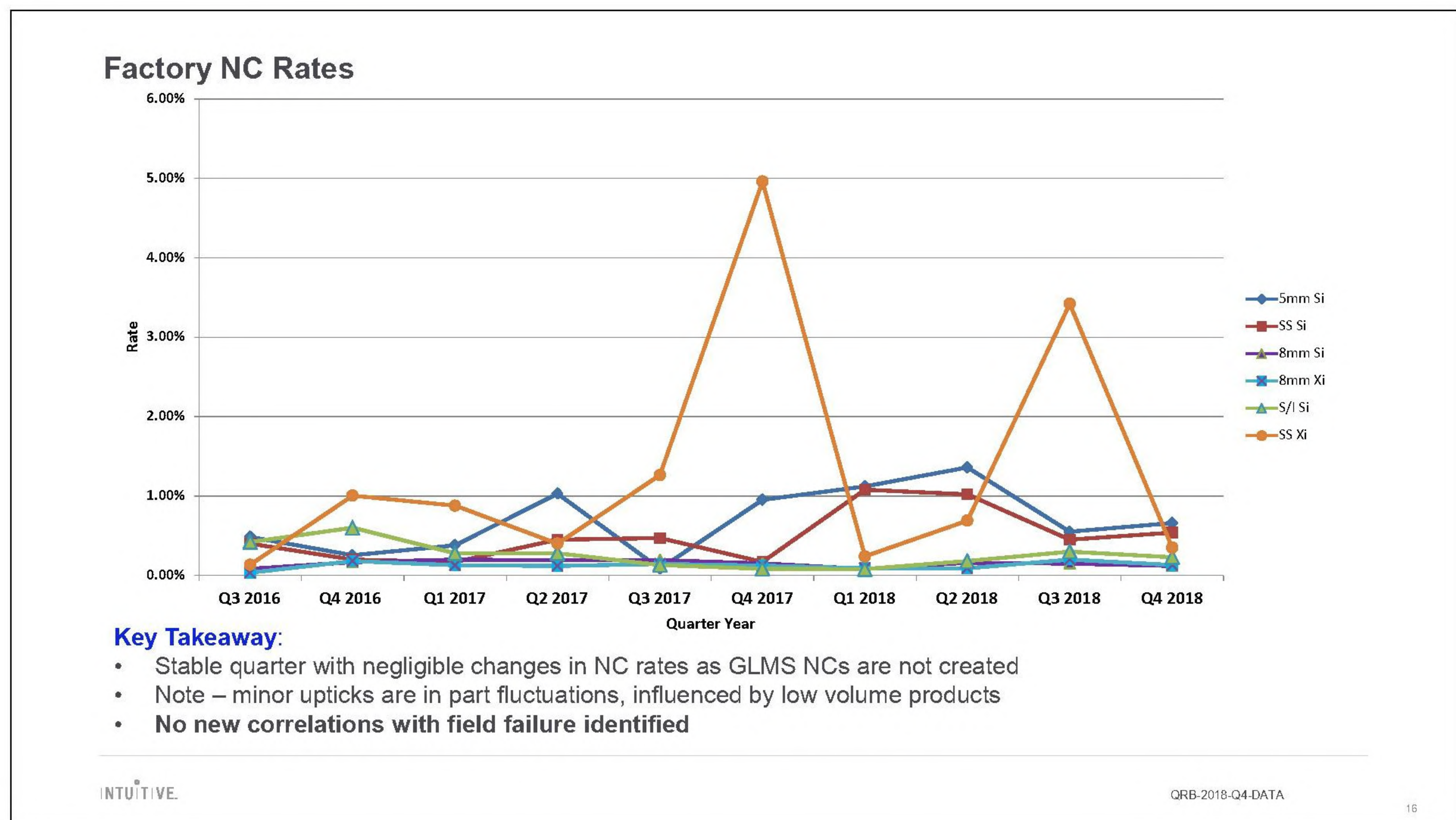
Active Investigations (pre-MCF):

- MCS 1.5
 - Cutting Performance & Reliability Improvement
- Investigate “Could Not Reproduce” and “NTF” RMA's
 - Soon to be largest contributing RMA Diagnosis Code

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Q4'17 Xi SS spike was due to MX line validation

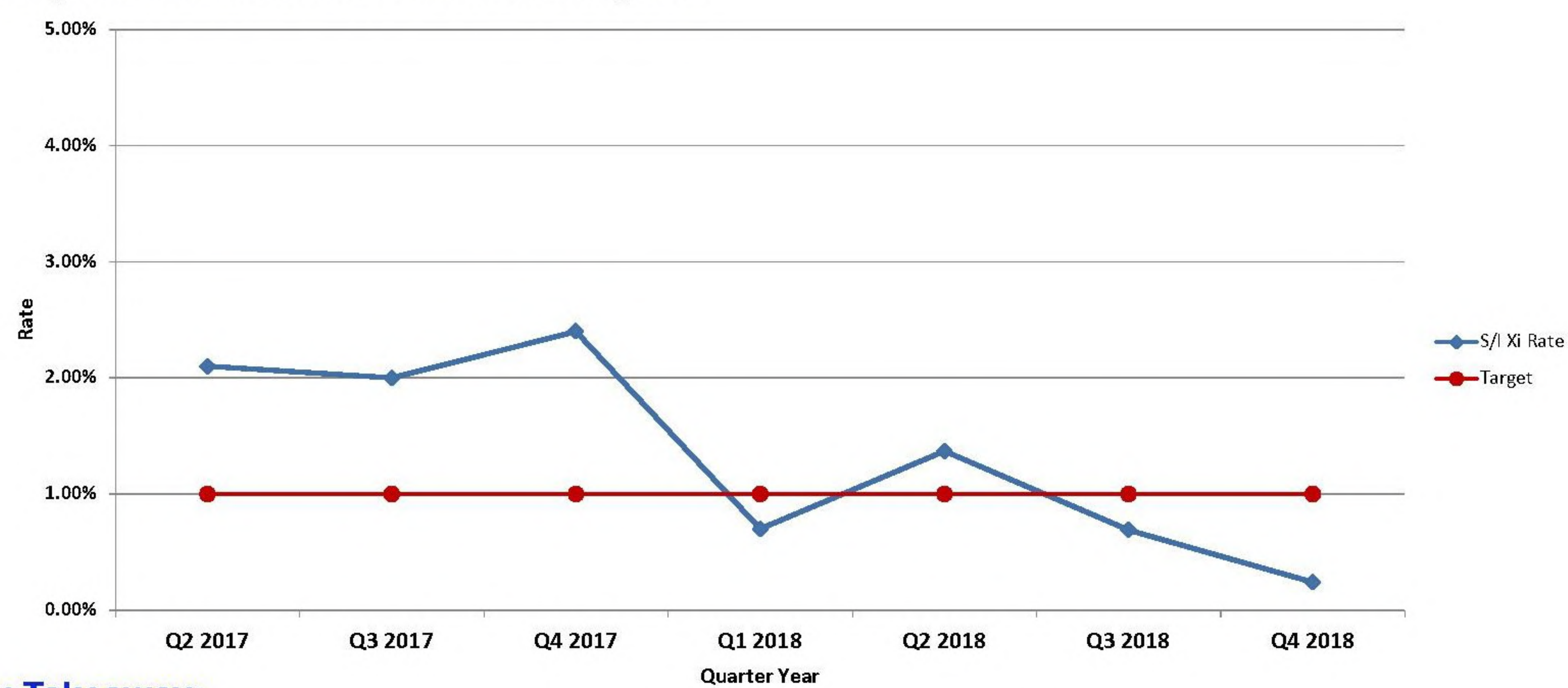
GLMS Discrepancies are being addressed thru DNs. NCs will now only be created for damaged labels, etc. They were previously made for incorrect values entered or excess prints.

8mmSi & 8mmXi: GLMS discrepancies and Xi/Si MCS main tube 90G PEEK bending

S/I Si: Increase in damaged boxes and FQI excess lubricant inside tube

Note - Upticks are in part fluctuations, influenced by low volume products

Factory NC Rates for Xi Suction Irrigator



Key Takeaway:

- Q4 2018 – continues to decrease due to increase in production in MX
- Final Manufacturing Review (FMR) date pushed out (Q2 2019 – pending CAPA 31739 closure).
- CAPA 31739 / MCF-18-055 / PIR2018-008 initiated for cuts on suction seal (Q2-18)

SP I&A RMAs

Instruments

SP RMA Trend

	2018 Q4
da Vinci SP # RMAs	5
# Procedures	228
RMA Rate	2.19%



Wrist Drive Cable pulled out of crimp – team is working on a fix

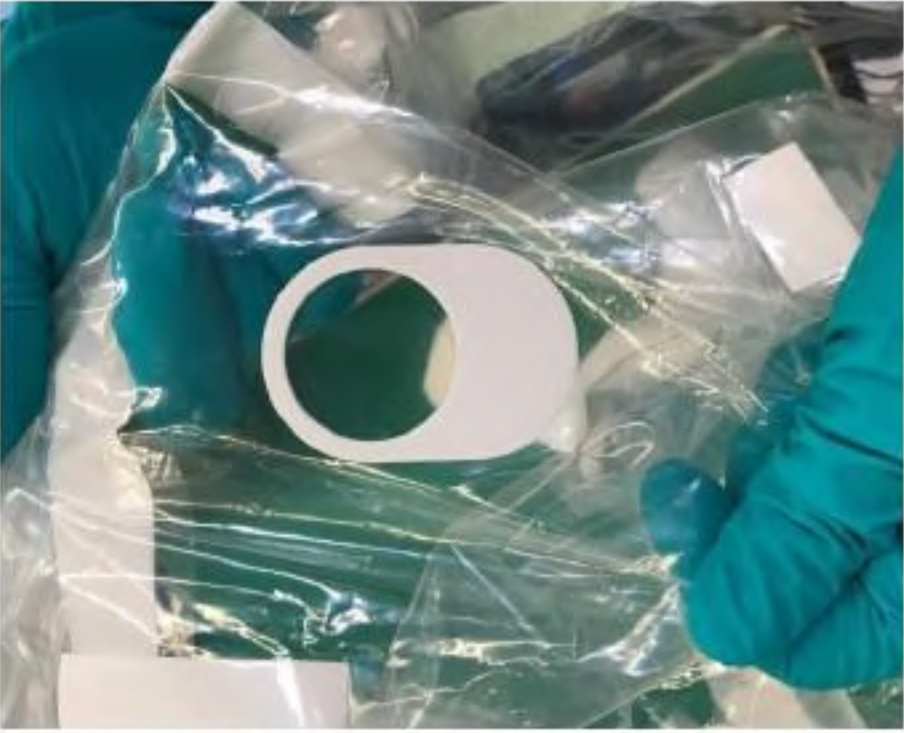


Broken Grip Tips (mishandling)

Accessories

SP RMA Trend

	2018 Q4
da Vinci SP # RMAs	7
# Procedures	228
RMA Rate	3.07%



EDF 70046: Loose magnet washer



Entry Guide ultrasonic welder, a potential contributor, repaired to prevent component binding (NC 4028052, EE 5048620, & MPI clarification ECO C217942

Non RMA – Field Issues

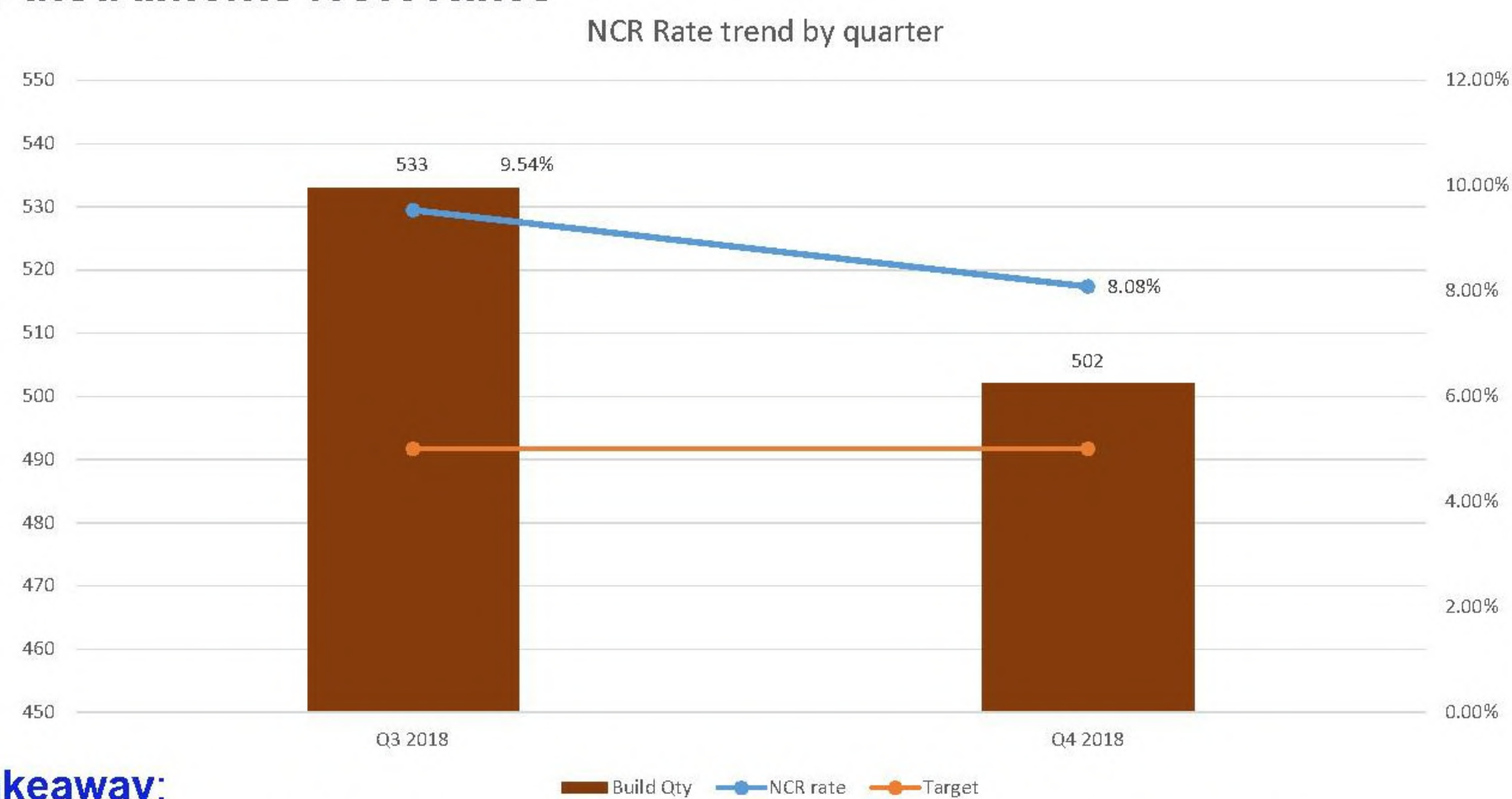
- PIR2018-019: Drape Tears

Key takeaways

- SP System is new and procedure volumes low
- Continue to monitor RMAs

Entry Guide ultrasonic welder, a potential contributor, repaired to prevent component binding (NC 4028052, 9/28/18, EE 5048620, 10-1-18 & MPI clarification ECO C217942, 11/21/18)

SP1098 Instruments NCR Rates



Key Takeaway:

- SP1098 instruments PPQ completed in June 2018. APL September 2018
- High NCR rate given a new line. Manufacturing improvements such as replacing EFT parts and increasing PMC frequency, improving manufacturing spec limits for tensioning to address slack issues, resolving component level issues at supplier, technician training to improve NCR rate.
- Final Manufacturing Review (FMR) in early 2020

Summary

- Q4 2018 RMA rate is stable
- Increase in Could Not Reproduce, especially for Si, but with no particular attributable cause
- All other top diagnoses are relatively stable or decreasing
- Projects completed or in place to address top issues with further improvement expected as rollout continues
 - Bent, bent severely, and broken grips
 - Input Disks
 - MCS Tube Extension Bending/Bulging
 - Grip and Pitch Cables
 - expect closure given reduced/ negligible RMA rate
 - justification will accompany the applicable ECOs
- No new Items to escalate

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Questions/Actions

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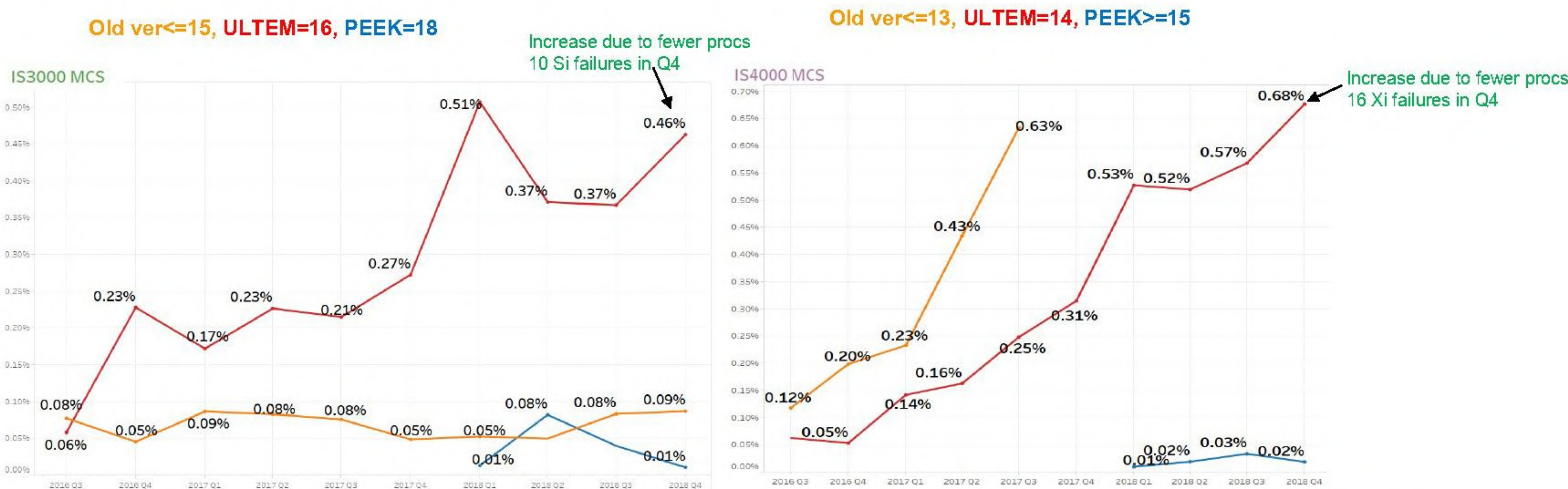
Backup Slides

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MCS Tube Extension Performance – Breaking/Cracking/Damaged Keys



Key Takeaways:

- Ultem overmolded tube extension cracking failure (MCF-17-044 / EDF-2017-0040, completed)
- Improvements on the key features (MCF-16-075 / EDF-2017-0025, completed):
- PEEK performing well vs. Ultem and older versions in regards to cracking + non-intuitive motion

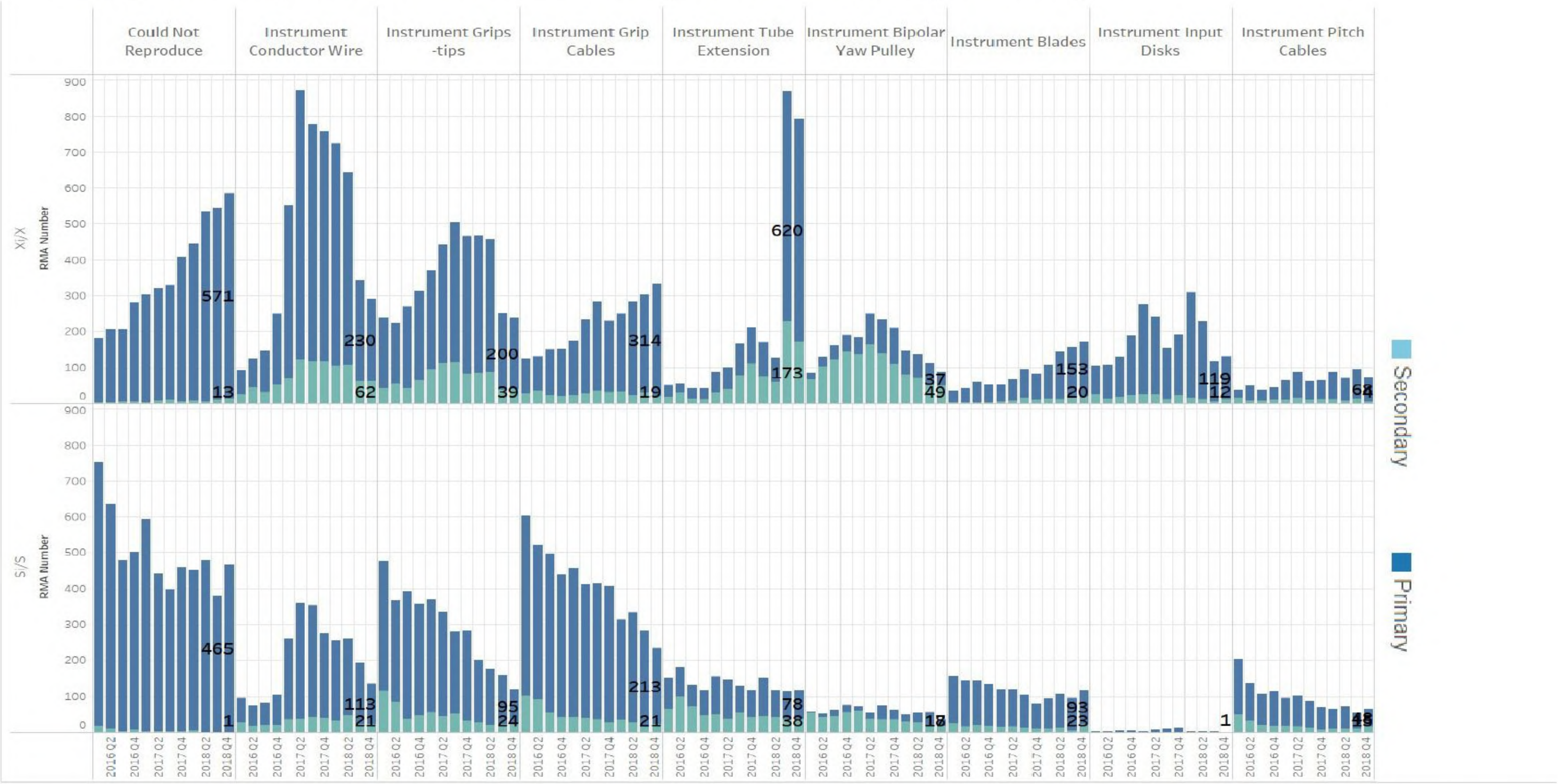


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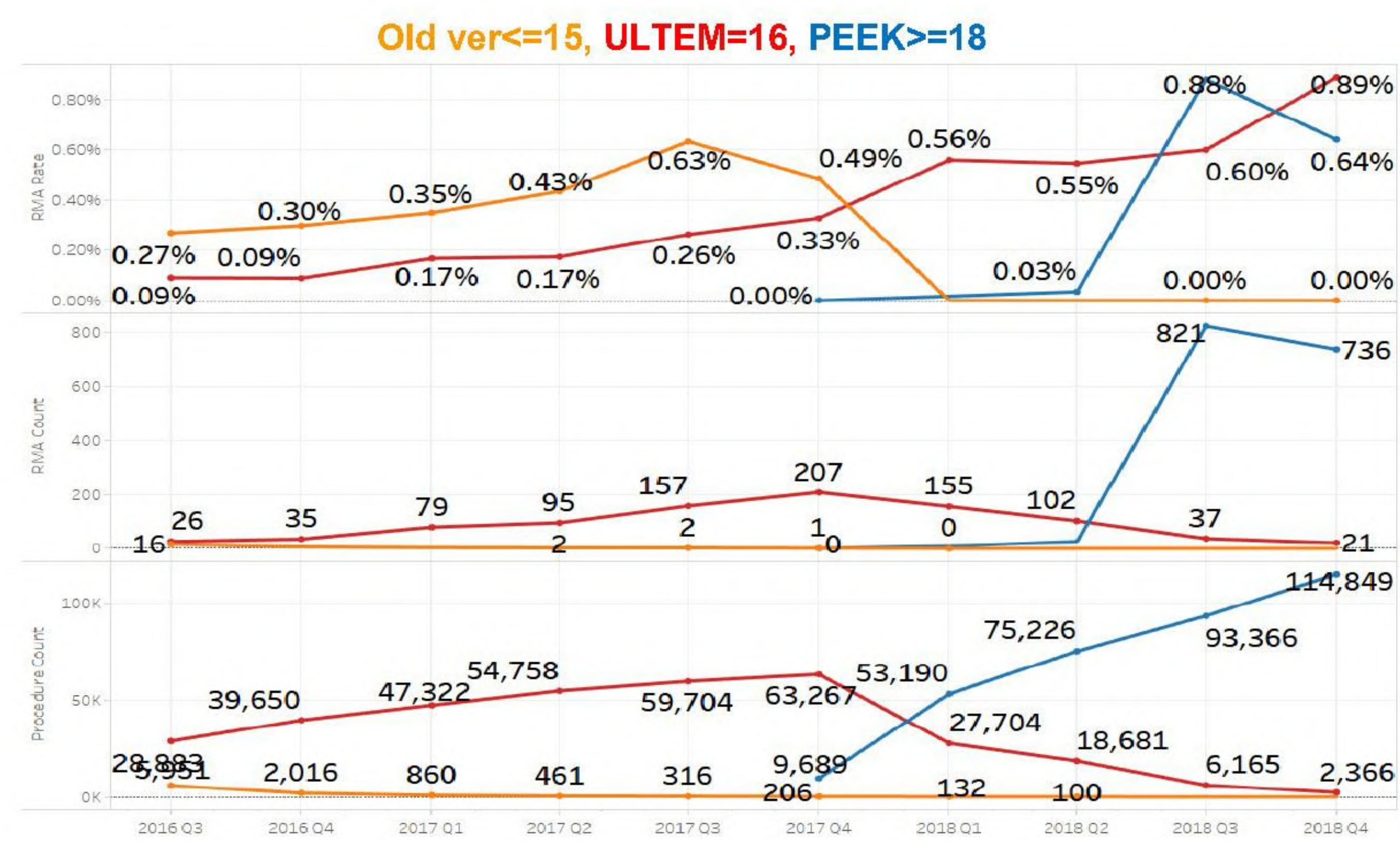
Diagnoses by RMA Volume - Primary and Secondary Findings



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IS3000 MCS Tube Extension Performance



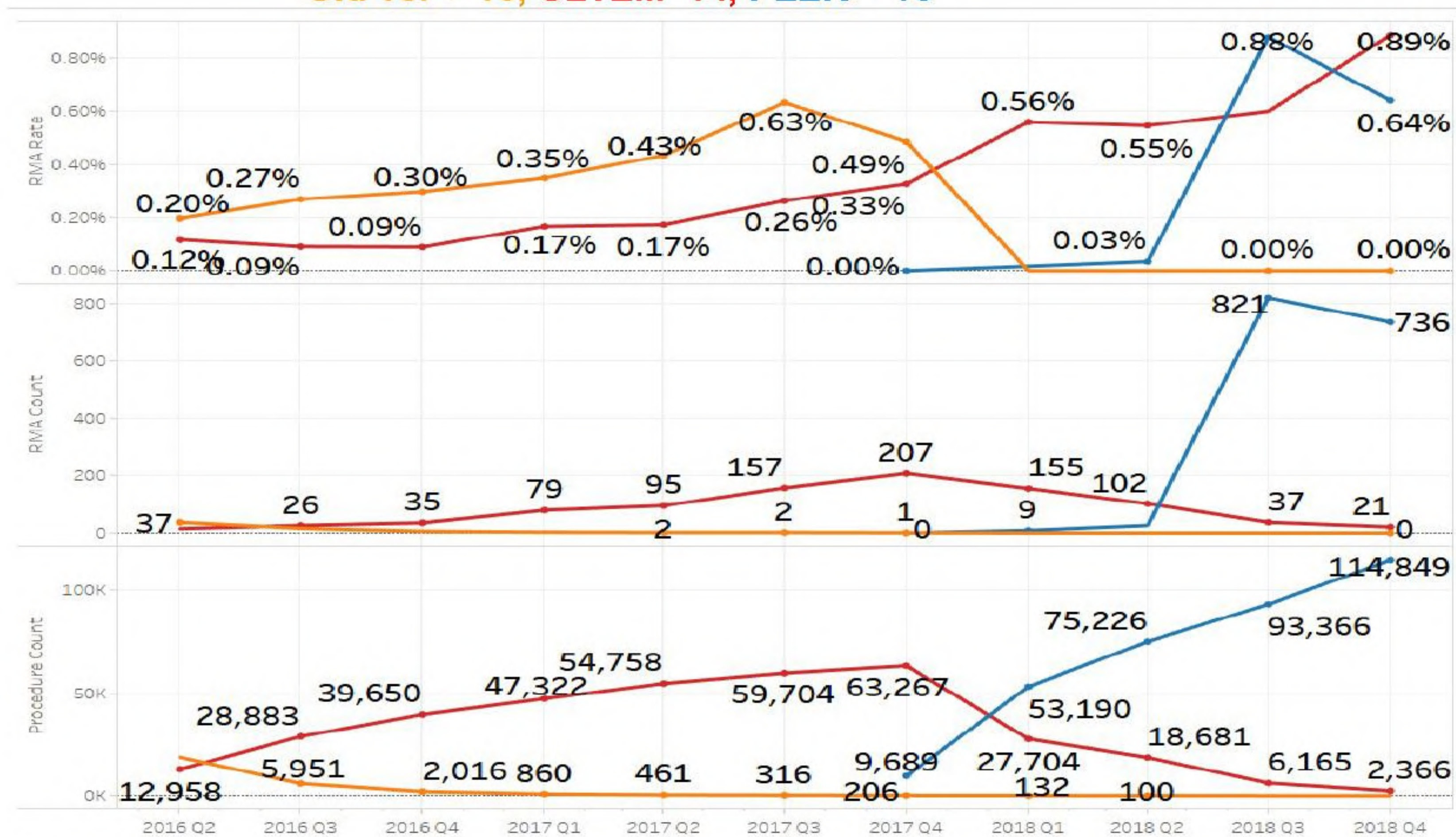
Key Takeaways:

- Rate increase attributed to lower procedure volume and higher number of returns

RW: Phase 1 changes were lumped together under MCF-17-044.

IS4000 MCS Tube Extension Performance

Old ver<=13, ULTEM=14, PEEK>=15



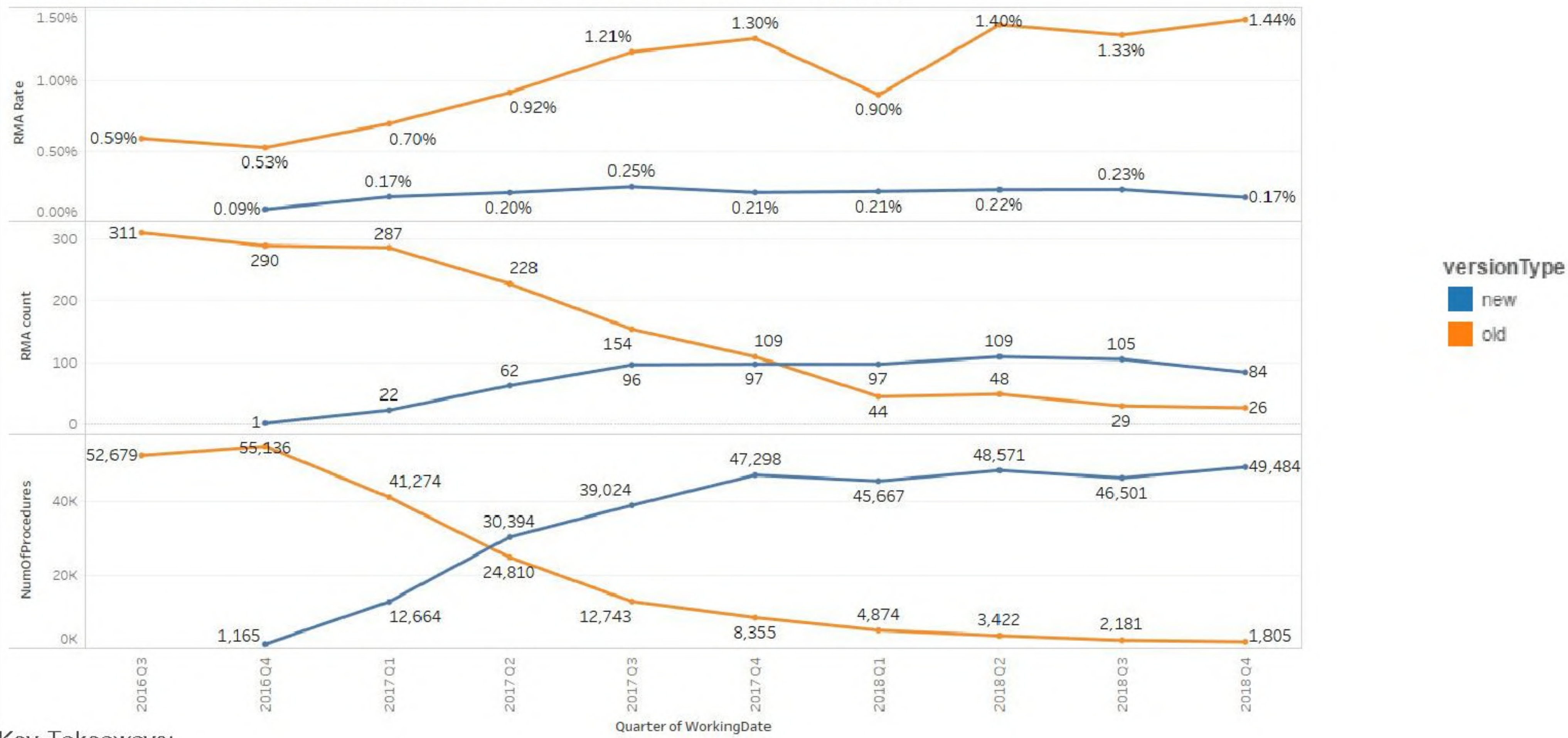
Key Takeaways:

- PEEK increase due to bending/bulging of the PEEK 90G units

RW: Phase 1 changes were lumped together under MCF-17-044.

Overall Performance (Si FBF)

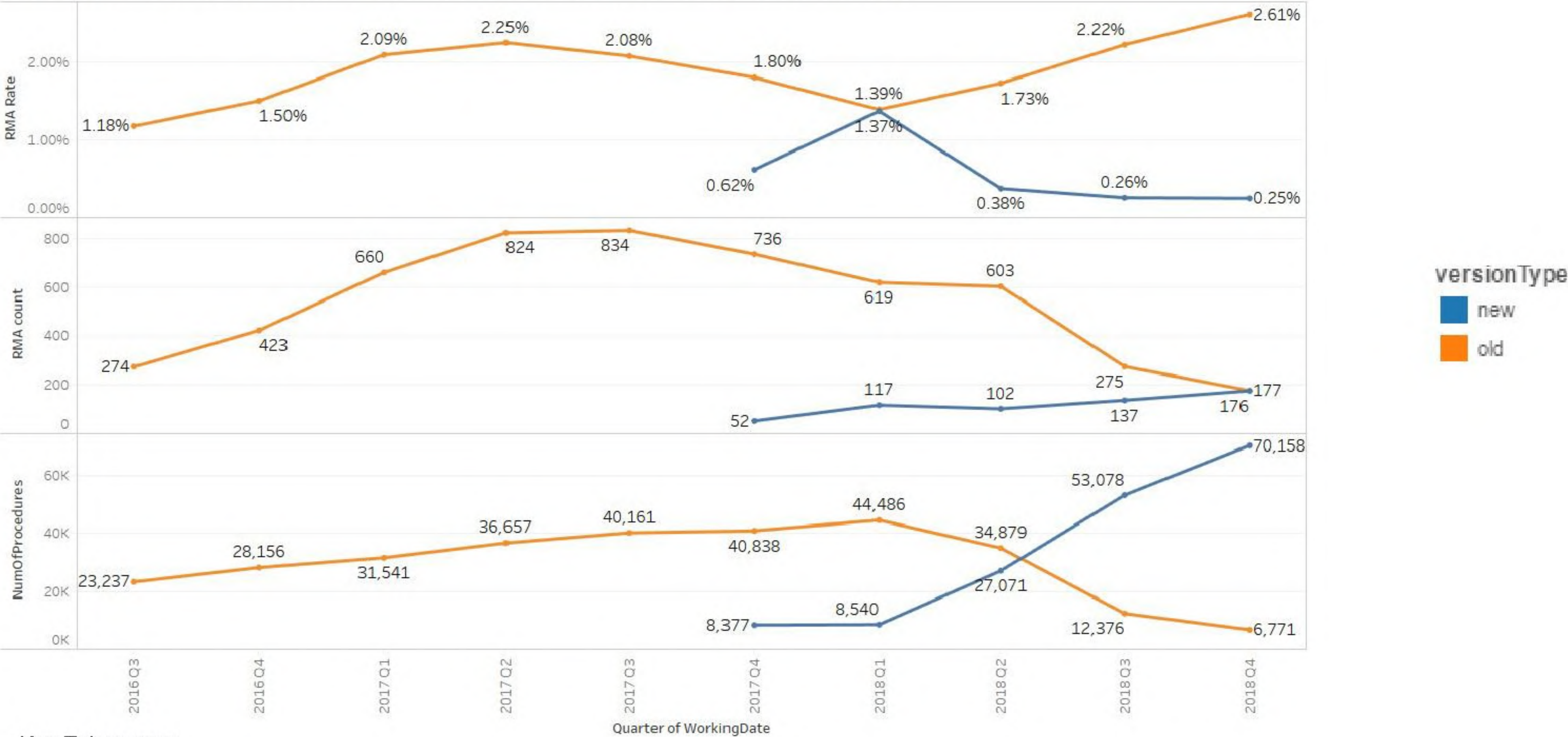
Procedure Count and RMA Number by Specific Instrument Part Number
(where: Diagnosis = ALL and Diagnosis Detail = ALL | New PartNumber-Ver = 420205-13 (includes all versions after that))



- Key Takeaways:
- New Si FBF design has lower RMA rates overall

Overall Performance (Xi FBF)

Procedure Count and RMA Number by Specific Instrument Part Number
(where: Diagnosis = ALL and Diagnosis Detail = ALL | New PartNumber-Ver = 470205-15 (includes all versions after that))

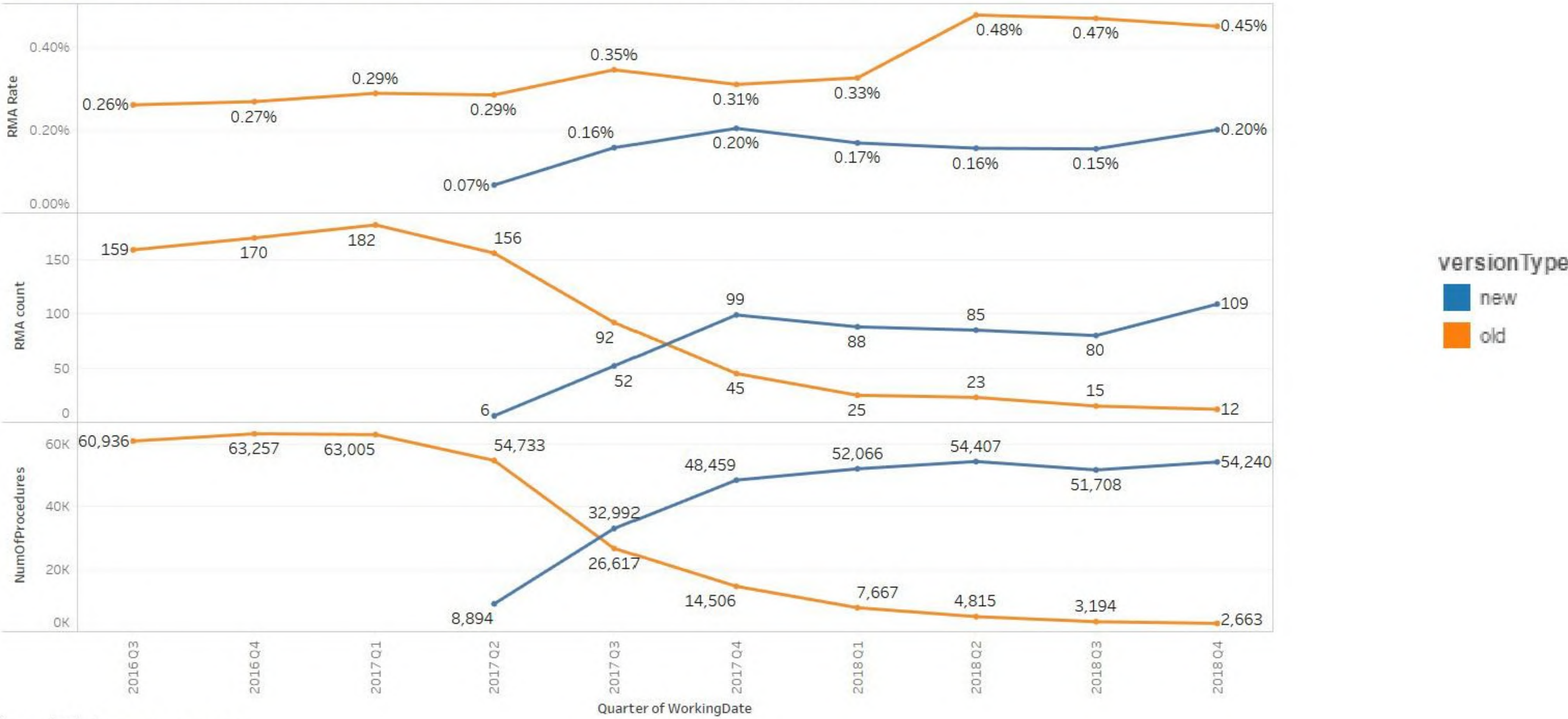


Key Takeaways:

- New Xi FBF design has lower RMA rates overall after addressing conductor wire dislodged and broken grips

Overall Performance (Si ProGrasp)

Procedure Count and RMA Number by Specific Instrument Part Number
(where: Diagnosis = ALL and Diagnosis Detail = ALL | New PartNumber-Ver = 420093-12 (includes all versions after that))

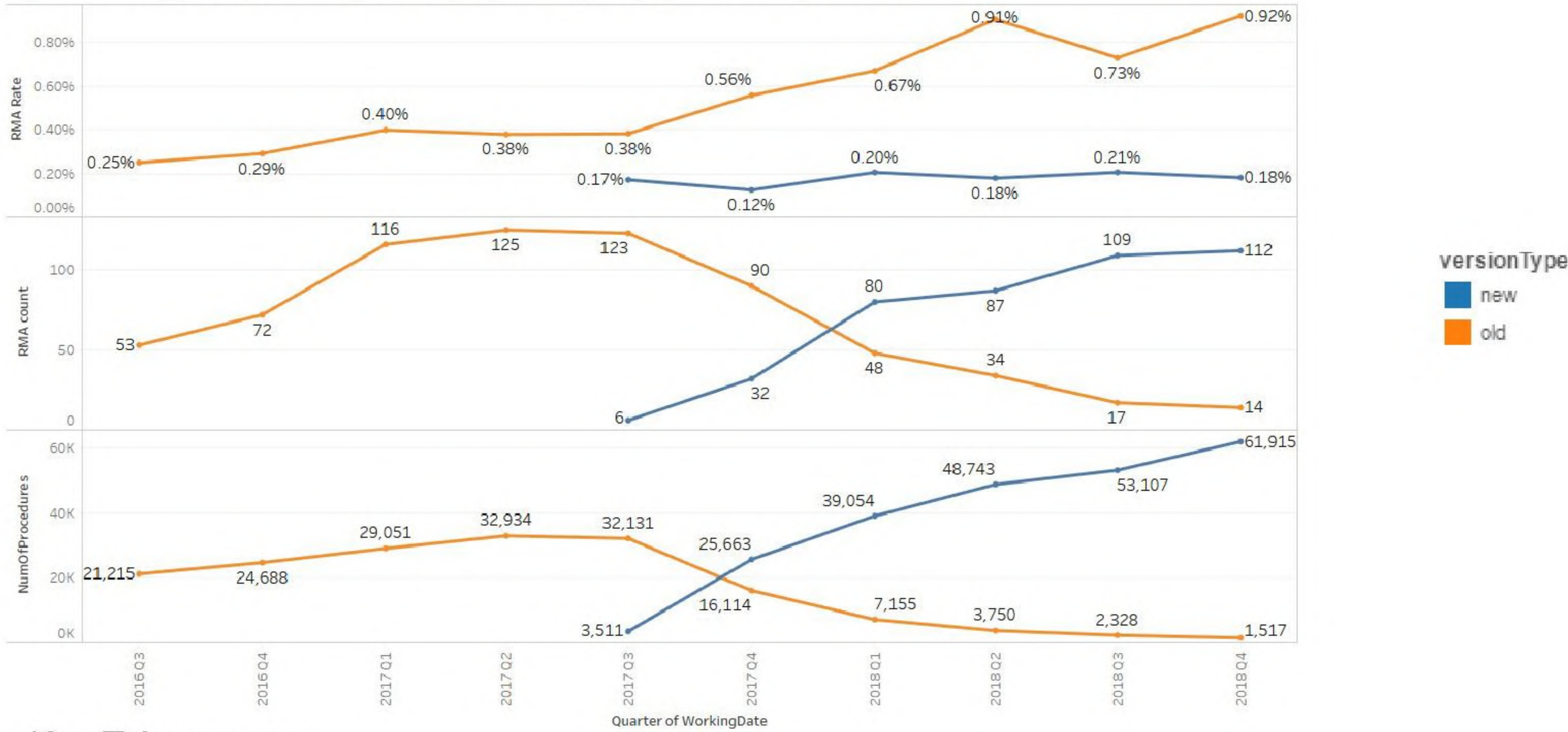


Key Takeaways:

- New Si ProGrasp design has lower RMA rate overall

Overall Performance (Xi ProGrasp)

Procedure Count and RMA Number by Specific Instrument Part Number
(where: Diagnosis = ALL and Diagnosis Detail = ALL | New PartNumber-Ver = 470093-10 (includes all versions after that))

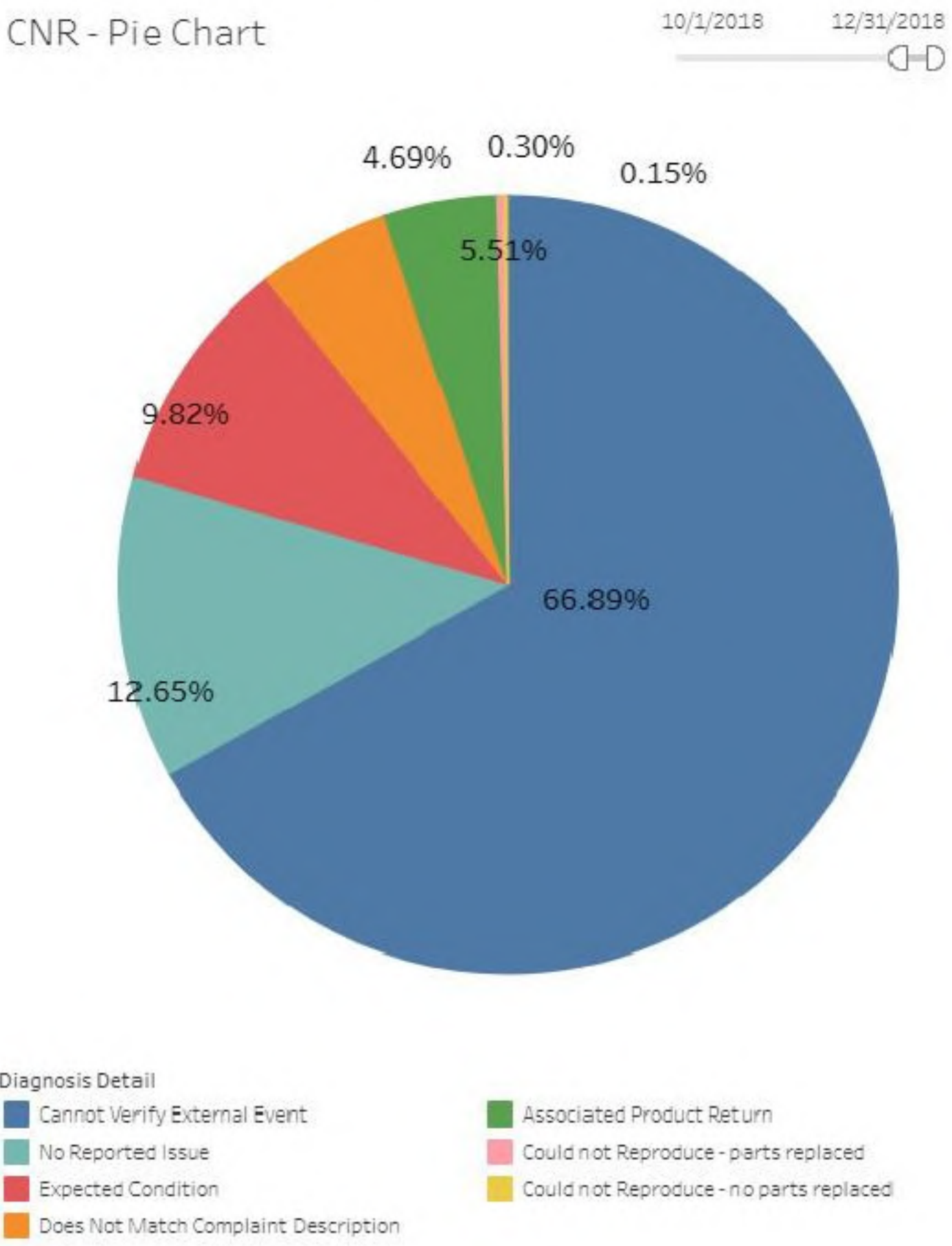


Key Takeaways:

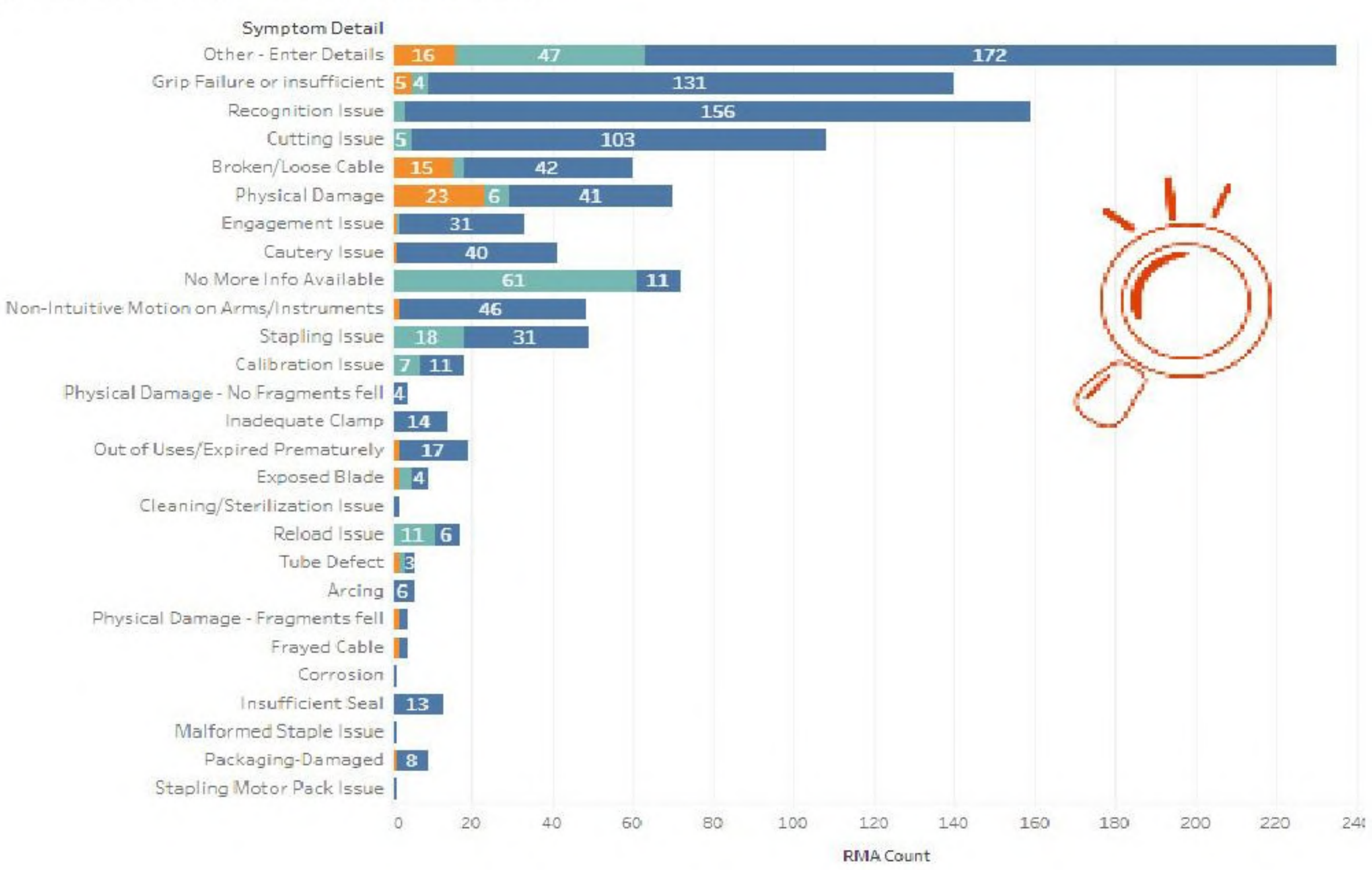
- New Xi ProGrasp design has lower RMA rate overall

Diagnosis: Could Not Reproduce

CNR - Pie Chart



CNR- Pareto by Customer Reported Symptom Detail



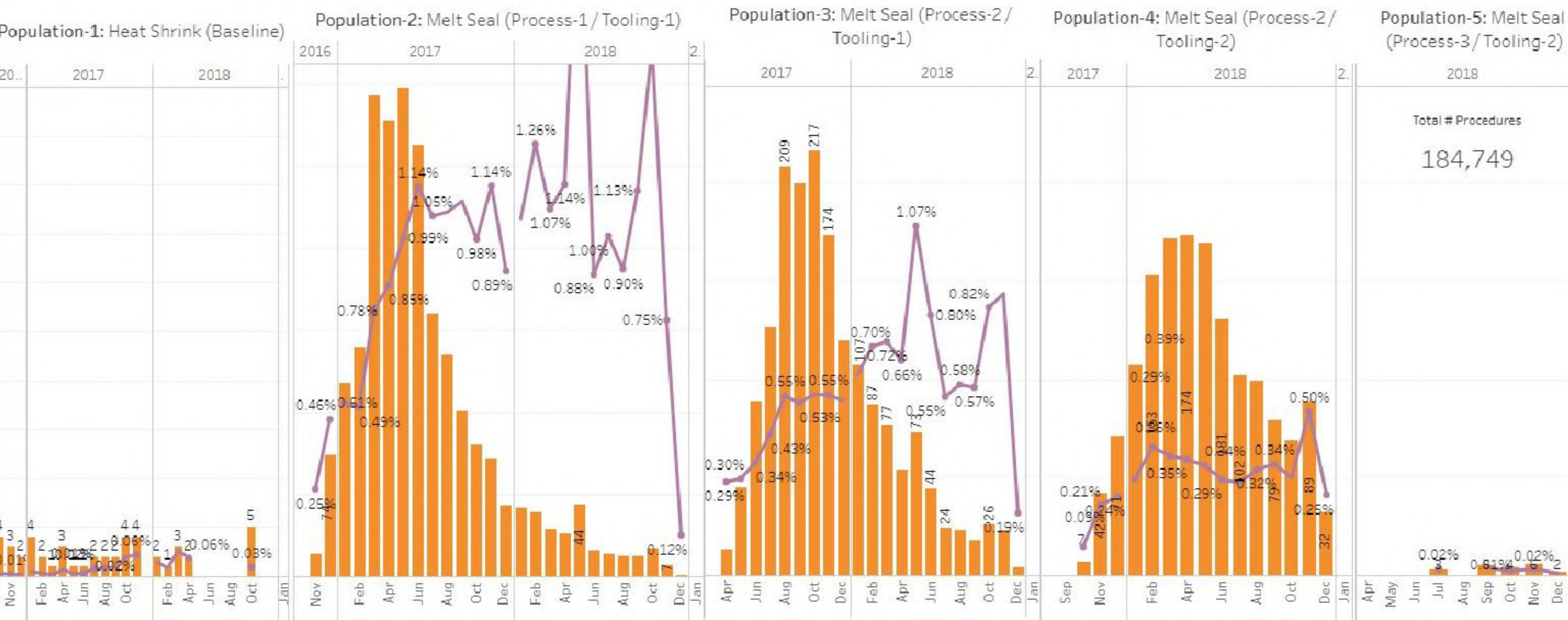
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Diagnosis: Instrument Conductor Wire - Dislodged

RMA Count and Rate (Normalized by Distinct Procedure Count) for Conductor Wire - Dislodged (2016-YTD; IS2000 System procedure count **not** included)



Key Takeaways:

- MCF-17-066 / EDF 1017 latest change on Population 5 (Process-3, long seal)
- Implemented on all Xi Bipolar products
- Sub population Monitoring of Xi is in progress, Si Bipolar implementation completed

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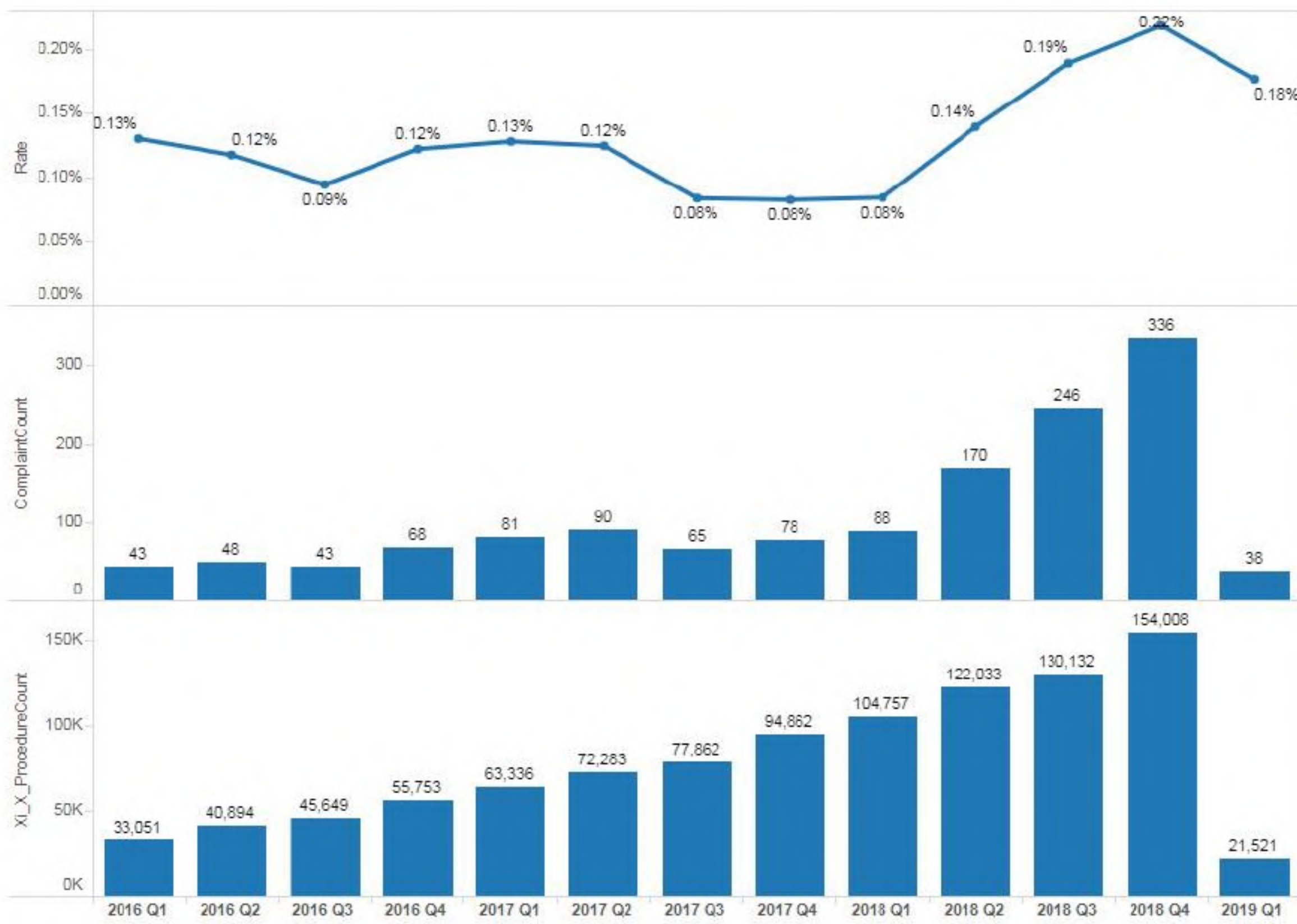
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Instrument Engagement

EDF 66990 Complaint Rate from 1/1/2016

System Model: da Vinci Xi, da Vinci X



Engagement failure defined as:

Data Description:
Complaint/RMA data is from 2016. Complaint != No and Systemname like 'sk%' or systemname like 'sl%') and (PhoneNotes like '%22020%' or PhoneNotes like '%engage%' or PhoneNotes like '%sterile%adapt%') or PhoneNotes like '%redrap%' or PhoneNotes like '%re-drap%' or ErrorCode like '%22020%') and PhoneNotes not like '% 282 %' and (Z2_Materialname is null or Z2_MaterialName like '%sum%') and ((CustomerSymptom like '%manipulator%' and SymptomDetail like '%yellow%') or SymptomDetail like '%engage%')

Rate of Escalation = 0.4%
Quarterly rate is currently below rate of escalation, continue to monitor per EDF 66990 criteria.